United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

UNITED FOOD AND COMMERCIAL WORKERS LOCAL 1776 & PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, et al., Plaintiffs, v. TEIKOKU PHARMA USA, et al., Defendants.	Case No. 14-md-02521-WHO **ORDER ON PENDING MOTIONS**

Currently before me are the parties' motions for summary judgment and motions to exclude expert testimony. Defendants move for summary judgment as to all of plaintiffs' claims, but as described below plaintiffs have significant evidence that Watson could have (if not would have) ultimately prevailed in the '529 litigation and a cognizable (if not disputed) theory of alternate injury in a but-for world. Defendants' motion is DENIED.[1] Plaintiffs more narrowly move for partial summary judgment that they have satisfied the "contract, combination, or conspiracy" element of their Section 1 and Section 2 claims (defendants do not oppose) and also to define the relevant antitrust market as the market for generic and brand 5% lidocaine patches. Rejecting defendants' arguments in support of an essentially unlimited market for pain relief products, I agree that plaintiffs have shown on undisputed material facts that the relevant market is the market for 5% lidocaine patches and GRANT their motion.[2]

[1] Defendants' alternate motion for partial summary judgment for a finding of fact under Rule 56(g) that Watson could not have launched its generic earlier than December 17, 2012 is not opposed by plaintiffs and is GRANTED.

[2] On October 31, 2017, I signed a stipulated dismissal, dismissing with prejudice the claims asserted by Retailer Plaintiffs Walgreen Co., Safeway Inc., Kroger Co., HEB Grocery Company L.P., Albertson's LLC., CVS Pharmacy, Inc., Rite Aid Corp., and Rite Aid Hdqtrs Corp. against

The general background and history of this litigation is well known and laid out in my prior orders. Dkt. Nos. 117, 670. The facts material to the determination of these motions, both undisputed and disputed, will be addressed below.

LEGAL STANDARD

Summary judgment on a claim or defense is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In order to prevail, a party moving for summary judgment must show the absence of a genuine issue of material fact with respect to an essential element of the non-moving party's claim, or to a defense on which the non-moving party will bear the burden of persuasion at trial. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once the movant has made this showing, the burden then shifts to the party opposing summary judgment to identify "specific facts showing there is a genuine issue for trial." *Id.* The party opposing summary judgment must then present affirmative evidence from which a jury could return a verdict in that party's favor. *Anderson v. Liberty Lobby*, 477 U.S. 242, 257 (1986).

On summary judgment, the court draws all reasonable factual inferences in favor of the non-movant. *Id.* at 255. In deciding a motion for summary judgment, "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." *Id.* However, conclusory and speculative testimony does not raise genuine issues of fact and is insufficient to defeat summary judgment. *See Thornhill Publ'g Co., Inc. v. GTE Corp.*, 594 F.2d 730, 738 (9th Cir.1979).

DISCUSSION

I. DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

A. Defendants' Motion for Summary Judgment on All Claims

Plaintiffs' case rests on two theories of antitrust injury causation: (i) absent the large reverse payment, Watson would have launched at-risk; and (ii) absent the large reverse payment

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Defendant Endo Pharmaceuticals Inc. However, as the defense arguments are asserted by all three defendants against all of the claims asserted by plaintiffs, nothing in this Order appears to be impacted by the Stipulated Dismissal.

the parties would have reached an alternative "no payment settlement" giving Watson early entry into the market. Pls. Oppo. to MSJ [Dkt. No. 819] at 1. Defendants argue that summary judgment must be granted in their favor on plaintiffs' first theory because Watson's infringement of the '529 patent breaks the "chain of causation" as illegal activity and cannot support an antitrust claim. Plaintiffs counter that under Ninth Circuit case law, the chain cannot be broken by the '529 patent, but even it if could, plaintiffs have ample evidence from which a reasonable juror could determine that Watson would have prevailed in the patent litigation. As to plaintiffs' second theory, defendants argue that the "hypothetical" settlement proposed by plaintiffs is not legally cognizable and not supported by evidence in the record. Plaintiffs counter that numerous courts have recognized that hypothetical settlements are an acceptable basis for causation and that there is significant evidence in the record that a reasonable juror could rely on to find that, absent the reverse-payment settlement agreed-to in this case (hereafter Settlement), another settlement would have been reached to allow Watson early-entry to the market.

1. At-Risk Launch Theory

a. Necessity to Address Watson's Chances of Success in the '529 Patent Litigation

Plaintiffs argue that they need not show that Watson would have likely won the '529 patent litigation in order to prevail at trial in this case. They rely primarily on the Supreme Court's decision in *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). There, the Court explained that "it is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham . . . . An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." *Id.* at 2236; *see also* 3 Philip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 2046d2 (Supp. 2016) ("The size of the payment operates as a surrogate for direct patent-law-based questions about patent quality. Indeed, payment size may actually be a more reliable indicator to the extent it reflects the settling parties' market-based judgment about the patent's prospects in a fully litigated infringement suit."). According to plaintiffs, that is exactly the shape of this case; the reverse settlement payments are unexplained by legitimate factors (such as avoidance of litigation costs or

the provision of other services) and are indisputably large. Plaintiffs also rely on their expert, Professor Einer Elhauge, who opined that if Endo thought it had more than a 15.1% chance of winning, Endo would not have rationally agreed to the Settlement because its expected profits from continuing to litigate would have exceeded its profits from the settlement. Elhauge Report, Declaration of Dena Sharp [Dkt. No. 819] Ex. 1 [Dkt. No. 819-2] ¶¶ 6, 8, 147-48.

Recent decisions have limited the use of sole reliance on a large and unexplained reverse payment as a proxy for the weakness of the underlying patents to cases, like *Actavis*, that are brought by the FTC. In a detailed analysis, the district court in *In re Wellbutrin XL Antitrust Litig*., 133 F. Supp. 3d 734 (E.D. Pa. 2015), as affirmed by the Third Circuit, concluded that the Supreme Court's admonition in *Actavis* that "it is normally not necessary to litigate patent validity to answer the antitrust question" was limited to the context of an action brought by the FTC under the FTC Act's "more relaxed" "likely to" causation standard. 133 F. Supp. 3d at 764. The court concluded that where private litigants are proceeding under the Clayton Act, that Act's more stringent "proximate cause" standard requires showing that it was the settlement that precluded competition and not the patents. *Id*. If that could not be proved, the patent protection provided to the brand manufacturer (and that manufacturer's right to exclude) cuts off the chain of causation. "In other words, if an agreement only replicates the effect of the underlying patent litigation, any exclusion resulting from that agreement must be caused by the underling patent." *Id*. at 765; *see also In re Wellbutrin Xl Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 169 (3d Cir. 2017) (recognizing what while the "size of a reverse payment may have some relevance in determining how confident a litigant is in the strength of its case" it could not standing along provide a "surrogate" for the weakness of the challenged patent).[3]

Similarly, the First Circuit in *In re Nexium (Esomeprazole) Antitrust Litig*., 842 F.3d 34

[3] The district court considered whether plaintiffs had introduced evidence in the antitrust case showing that a "reasonable juror could find" that the generic defendant would have prevailed in the underlying patent litigations. *Id*. Because defendants' expert presented unchallenged testimony that the generic had only a 20% chance of success in one of the cases "no reasonable juror" could have found that the generic would have succeeded. *Id*. at 767. The Third Circuit affirmed. 868 F.3d at 169 ("no reasonable jury could conclude that Anchen would have been more likely than not to prevail.").

(1st Cir. 2016) rejected plaintiffs' contention that they were impermissibly prevented from putting on evidence regarding multiple theories of causation, including a theory based on an assertion that the generic manufacturer would have won the Paragraph IV patent litigation, by the district court's summary judgment ruling. In reaching that conclusion, the First Circuit accepted the proposition that "the plaintiffs did not present such evidence that the brand-name's patents would have been declared invalid or that an at-risk launch would not have infringed the patents. And without such evidence, the 'patent served as an independent regulatory bar to [a generic's] launch.'" *Id*. at 63 (*quoting In re Wellbutrin XL Antitrust Litig*., 133 F. Supp. 3d at 767); *see also id*. ("The district court thus did not err by requiring some evidence of the patents' invalidity or noninfringement before allowing the plaintiffs to pursue an at-risk launch theory."); *cf. Apotex, Inc. v. Cephalon, Inc*., No. 2:06-CV-2768, 2017 WL 2473148, at *8 (E.D. Pa. June 8, 2017) ("The clear import of Nexium and Wellbutrin is that a plaintiff must offer some evidence of non-infringement or patent invalidity in order to proceed on an at-risk launch theory of causation. The fact that the patent in question has been found to be invalid and non-infringed is relevant evidence on that required proof. Against this backdrop, I agree with Plaintiffs that evidence of a patent's subsequent invalidation is highly probative to the lawful launch question.").[4]

Plaintiffs respond, first, that these cases are inapposite under binding Ninth Circuit case law and that the existence of the '529 patent does not make the but-for at-risk sales of Watson illegal. Plaintiffs point out that under the Hatch-Waxman Act and Paragraph IV litigation scheme, generic entrants are allowed into the market prior to patent expiration or invalidity. They need only secure an ANDA approval and have made the Paragraph IV certification that the patent is invalid, unenforceable, or will not be infringed. *See Anesta AG v. Mylan Pharm., Inc*., No. CV 08-889-SLR, 2014 WL 3976456, at *2 (D. Del. Aug. 14, 2014) ("although their launch was at

[4] As broader support for their argument that a valid patent cuts off plaintiffs' antitrust claims, defendants rely on a line of cases holding that plaintiffs cannot prove antitrust injury where an existing law or regulation would have prevented the competition that was allegedly foreclosed by collusive conduct. *See* Defs. Mot. SJ at 7 & n.9. Plaintiffs persuasively distinguish those cases because here, Watson would have been expressly permitted by regulation to enter the market upon ANDA approval and because patent law does not require a competitor to obtain permission *before* entering the market, but instead allows the patentee to seek an injunction stopping that competition.

risk, it was not illegal when it took place").

Plaintiffs then rely on *Memorex Corp. v. Int'l Bus. Machines Corp.*, 555 F.2d 1379 (9th Cir. 1977). There, Memorex brought antitrust claims against IBM who in turn asserted as a defense that Memorex's own wrongful acts (theft of IBM's trade secrets) barred Memorex's antitrust claims. The Ninth Circuit held "that illegality is not to be recognized as a defense to an antitrust action when the illegal acts by the plaintiff are directed against the defendant. A wrongful act committed against one who violates the antitrust laws must not become a shield in the violator's hands against operation of the antitrust laws." *Id*. at 1382. That concept, however, was "particularly true when the defendant has other remedies available," namely a counterclaim against Memorex for the alleged misappropriation. *Id*. Plaintiffs argue that the principle recognized in *Memorex* is particularly relevant here because there is no allegation that plaintiffs committed any wrong, only a thin allegation that one of the alleged antitrust violators may have (if the patent was ultimately held to have been valid) been making sales that would expose it to damages and an injunction. However, I do not find *Memorex* as persuasive as plaintiffs contend. Here, it is not defendants' attempting to use plaintiffs' illegal conduct, or even Watson's conduct, as a shield against antitrust liability. Instead, the question is what amount of evidence (if any) must plaintiffs present to substantiate their assertion that defendants' reverse settlement was motivated by Endo and Teikoku's concerns that their patent rights were at serious risk in light of Watson's patent litigation.[5]

More persuasive are plaintiffs' criticisms of the *Wellbutrin* and *Nexium* decisions, and also their argument that they have, nevertheless, met the burdens imposed on plaintiffs in those cases.

[5] Plaintiffs also rely on a series of cases that rejected the related but distinct concept that the regulatory requirements of the Hatch/Waxman Act (the 30-month automatic stay and the requirements of securing ANDAs) could be the cause of the plaintiffs' antitrust injury instead of the conduct of the defendants in engaging in inequitable conduct before the PTO and filing sham patent litigation cases. *See, e.g., In re Metoprolol Succinate Direct Purchaser Antitrust Litig*., No. CIV.A. 06-52 (GMS), 2010 WL 1485328, at *7 (D. Del. Apr. 13, 2010); *In re K-Dur Antitrust Litig*., 338 F. Supp. 2d 517, 535 (D.N.J. 2004) (rejecting Hatch/Waxman Act as creating intervening cause of antitrust injuries defeating claims, but further recognizing that "conjecture" that at-risk launch "may have been improvident given the risk that the generic manufacturer might lose the patent suit and been liable for damages, is not this Court's concern on a motion to dismiss."). Defendants point out that those cases have been superseded on the point relevant here by the *Nexium* and *Wellbutrin* decisions.

I agree that those courts' reliance on the FTC being the plaintiff in *Actavis* to discount the "large and unexplained" reverse payment proxy for patent weakness standard adopted by the *Actavis* majority is not supported by anything said by the *Actavis* majority. So does the California Supreme Court, which in a thorough analysis of the *Actavis* decision concluded that "nothing in the United States Supreme Court's discussion of the legal rules at the boundary between antitrust and patent law hinged on the happenstance that the case under review involved a public prosecutor." *In re Cipro Cases I & II*, 61 Cal. 4th 116, 142 (2015), *reh'g denied* (July 8, 2015).

The *In re Cipro* court pointed out that the if a reverse payment settlement "only replicates the likely average result of litigation, any exclusion is a function of the underlying patent strength; if it extends exclusion beyond that point, this further exclusion from the marketplace—and the attendant anticompetitive effect—is attributable to the agreement." 61 Cal.4th at 150. In discussing a defendant's burden to demonstrate that a reverse payment settlement was procompetitive, the court later explained that "consideration of whether the agreement is justified as procompetitive will not turn on whether the patent would ultimately have been proved valid or invalid" because "[a]greements must be assessed as of the time they are made . . . at which point the patent's validity is unknown and unknowable." *Id*. at 158 (recognizing that "[j]ust as later invalidation of a patent does not prove an agreement when made was anticompetitive . . . later evidence of validity will not automatically demonstrate an agreement was procompetitive."). The court then acknowledged the Court's explanation in *Actavis* that an unexplained large reserve payment could provide a workable surrogate for a patent's weakness. *Id*. at 159. In sum, in explaining how the rule of reason analysis should play out in a reverse-payment settlement scenario under the Cartwright Act, the *Cipro* court recognized that evidence regarding the strength of the patent – assessed as of the time of the settlement – was important and also recognized that the existence of a large and unexplained reverse payment was, likewise, relevant evidence of a patent's weakness.

The *In re Cipro* court's conclusion, that patent validity and potential enforceability (*e.g.*, strength and potential infringement) needs to be considered but that it is not necessary for a plaintiff to show that the patents would ultimately be declared invalid or the generic determined

not to infringe, is not inconsistent with *In re Nexium*. In *Nexium* the First Circuit concluded the district court did not err by requiring plaintiffs to put forth "*some evidence* of the patents' invalidity or noninfringement before allowing the plaintiffs to pursue an at-risk launch theory." *In re Nexium*, 842 F.3d at 63 (emphasis added). "Some evidence" is not the same as requiring plaintiffs to prove that the generic defendant *would have* won, only that it *could have*. *See also Wellbutrin*, 868 F.3d at 169 ("On this record, then, no reasonable jury could conclude that Anchen would have been more likely than not to prevail."); *In re Opana ER Antitrust Litig*., 162 F. Supp. 3d 704, 720 (N.D. Ill. 2016) (rejecting contention on a motion to dismiss that plaintiffs "must plead that the Endo patents would ultimately have been invalidated or found uninfringed" as contrary to *Actavis*); *In re Aggrenox Antitrust Litig*., 94 F. Supp. 3d 224, 241 (D. Conn. 2015) (in a motion to dismiss, the "salient question" as "not whether the fully-litigated patent would ultimately be found valid or invalid—that may never be known—but whether the settlement included a large and unjustified reverse payment leading to the inference of profit-sharing to avoid the risk of competition.").[6]

Taken together, these cases stand for the proposition that a plaintiff must have "some evidence" that the generic could have won the patent litigation, a burden that plaintiffs have satisfied as discussed below. That showing will be weighed by the trier of fact, along with the other factors recognized as relevant by the Supreme Court in *Actavis*, such as the large and unexplained nature of the reverse payment itself.

In sum, I disagree that plaintiffs need to prove *in this case* that Watson *would have* won its patent litigations. That turducken is not only unappetizing as a matter of judicial efficiency, it is not required (or even suggested) by the *Actavis* opinion.[7] Instead, to put their at-risk launch theory of antitrust causation to the jury, plaintiffs must show "some evidence" that Watson could have

[6] The district court subsequently certified that question for interlocutory review. *In re Aggrenox Antitrust Litig*, No. 3:14-MD-2516 SRU, 2015 WL 4459607 (D. Conn. July 21, 2015).

[7] Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, Carl Shapiro, The Actavis Inference: Theory and Practice. 67 Rutgers U. L. Rev. 585, 617 (2015) (citing to *F.T.C. v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298, 1315 (11th Cir. 2012), *rev'd and remanded sub nom. F.T.C. v. Actavis, Inc*. (2013) 133 S.Ct. 2223(2013)).

won at trial before Judge Sleet or on appeal at the Federal Circuit. As discussed below, they have made that showing.

b. Watson's Chance of Success in the '529 Patent Litigation

Plaintiffs argue that significant evidence exists that a reasonable juror could rely on to find that Watson was likely to succeed in the '529 litigation including: (i) the large reverse payments themselves; (ii) Watson's positions in its Paragraph IV certification and during the '529 litigation; (iii) defendants' contemporaneous assessments that the '529 patent was weak; (iv) the testimony of the parties' respective experts that Watson would have won on appeal on invalidity defenses (as well as defendants' own experts concession that Watson would have won in the district court on infringement); and (v) the evidence of record in the '529 litigation.

No one disputes that the record in the '529 patent litigation was closed at the time of the parties' settlement. There had been a six day bench trial and the parties had submitted post-trial briefing. All that remained was for the Judge Sleet to issue his findings of fact and conclusions of law. As discussed below, for purposes of ruling on this motion, I conclude that plaintiffs have put forth significant evidence that Watson could have prevailed in the '529 litigation. While there is "some evidence" that Watson could have won on invalidity with respect to anticipation and non-infringement, I need not consider that evidence in-depth, because plaintiffs present stronger evidence on invalidity due to obviousness and unenforceability due to inequitable conduct.

i. Contemporaneous Evidence from Defendants

Plaintiffs note that in filing its ANDA application, Watson was required to and did certify that the '529 patent was invalid, unenforceable, and would not be infringed by Watson's planned generic. Watson spent over two years actively litigating the issues, contrary to defendants' current characterizations of Watson's chances of success.

The parties' contemporaneous statements, according to plaintiffs, also support a finding that Watson would have prevailed, including:

(i) Watson CEO's November 2011 earning call statements about its "strong litigation stance" and intent to start sales in 2012, Sharp Decl., Ex. 3 at 7. Defendants argue that these statements – made before the patent trial started – are irrelevant because they ignore the key

question here, what would have happened at and after trial and on appeal;

(ii) A July 2012 Watson memorandum that "the patents covering Lidoderm are not valid," that "Watson's legal assessment" was that the patents were weak, and that as such Watson had been preparing for launch upon FDA approval in July or August of 2012. *Id*., Ex. 4 at 1. The same memorandum described "Watson's legal assessment of the patent held by Endo as being weak." *Id*. at 3. Defendants note that the provenance of this "draft" disclosure statement is in dispute, as the purported author, Joe DosSantos denied having knowledge of it;

(iii) A February 2012 email from Endo General Counsel Caroline Manogue characterizing the patent as "very weak" and deposition testimony from Teikoku's outside counsel characterizing Endo's "negative impression" of the strength of the patent. Sharp Decls., Exs. 5 (email) and 6 (Shimoda Depo. Tr.) at 267-269. Defendants again downplay the significance of these documents, as they too were drafted before the patent trial, which they believe is the relevant point of focus; and

(iv) Draft Endo accounting letters from July 2012 that, "[w]hile the settlement with Watson was reached prior to the court's ruling, it was the view of [Endo's] management that there was a significant probability that the courts may find one or more of the patents to be invalid" and that "Watson and potentially other Companies may be able to launch a generic version of Lidoderm." *Id*., Ex. 7 at 11. Endo also admitted that it "believed a ruling in favor of Watson was very plausible, thus furthering our desire to settle." *Id*. Ex. 8 at 15. Defendants characterize these as having been written by individuals without knowledge of the '529 patent litigation and were prepared for review by others with actual knowledge "to fill in the gaps."

This evidence is relevant. Although its implications and importance are clearly disputed, it is significant enough – in combination with the expert opinions discussed below – to defeat defendants' motion for summary judgment.

ii. Expert Analysis

Plaintiffs rely most heavily – and defendants dispute most vigorously – on the testimony of plaintiffs' patent experts. After reviewing the trial record in the '529 litigation, those experts opine that Watson would have prevailed, if not in trial court then on appeal, on the issues of

invalidity due to anticipation and obviousness, as well as unenforceability due to inequitable conduct before the PTO.

Anticipation

Plaintiffs argue that Watson would have won on anticipation, maybe at trial but definitely on appeal, based on Watson's argument and evidence at trial that the '529 claims were anticipated by the "Takeda reference" that disclosed a lidocaine hydrogel patch.[8] Defendants challenge that assertion, arguing – as they did in the underlying '529 trial – that because the Takeda reference did not sufficiently disclose use of lidocaine in the patch, it did not "enable" a lidocaine patch. Defendants also argue that because Takeda did not disclose a particular concentration of lidocaine that could be used in the patch, the Takeda disclosure cannot support the "adequate description" requirement of an anticipation defense. Plaintiffs, in turn, dispute those contentions, arguing that the record below shows and arguments on appeal would have established that lidocaine was sufficiently disclosed. More particularly, as the Takeda reference discusses various embodiments, the teaching to use "expected clinical effect" was sufficient in conjunction with the fact that the Takeda concentration ranges overlap with the 5% lidocaine concentration claimed in the '529 patent, even if a 5% concentration was not expressly identified within Takeda for lidocaine. *Id.*[9]

For support, plaintiffs rely on Professor Martin Adelman who opines that based on the record before the trial court, Watson would have won on anticipation in light of the Takeda reference. Adelman Report (Declaration of Dena Sharp [Dkt. No. 819-1], Ex. 12 [Dkt. No. 819-

[8] The Takeda reference is U.S. Patent No. 4,695,465, entitled "Soft Patch." Takeda Patent (Sharp Decl., Ex. 16 [Dkt. No. 819-17]). The patent discloses 161 compounds that can be used in a hydrogel patch in various concentrations where the "concentration of the drug need only be that which exhibits the expected clinical effect, and in many instances ranges from about 0.01 to 14 weight percent, preferably 0.05 to 10 weight percent." *Id*. 3:30-34.

[9] Plaintiffs note that the burden to show non-enablement fell on Endo. *Amgen Inc. v. Hoechst Marion Roussel, Inc*., 314 F.3d 1313, 1355 (Fed. Cir. 2003) ("Thus, a court cannot ignore an asserted prior art patent in evaluating a defense of invalidity for anticipation, just because the accused infringer has not proven it enabled. Like the applicant in *ex parte* prosecution, however, the patentee may argue that the relevant claimed or unclaimed disclosures of a prior art patent are not enabled and therefore are not pertinent prior art. If a patentee presents evidence of nonenablement that a trial court finds persuasive, the trial court must then exclude that particular prior art patent in any anticipation inquiry, for then the presumption has been overcome.").

13]) ¶¶ 22-37.[10] Reviewing the evidence admitted at trial and the argument made by both Watson and Endo, Adelman opines that "a reasonable factfinder would conclude that Takeda discloses both lidocaine and discloses the use of lidocaine in a soft patch formulation in [the various disclosed ranges of concentration]." Adelman Report ¶ 37.[11]

Defendants counter with patent litigator Robert S. Frank, Jr., who disputes Adelman's conclusions and opines that Judge Sleet would have not found Takeda anticipating. Frank Report (Declaration of Daniel B. Asimow [Dkt. No. 786-1], Ex. [Dkt. No. 786-12], ¶¶ 48-49. Frank argues that in order for Watson to have won on anticipation, Judge Sleet would have had to credit Watson's expert (Walters) over Endo's expert (Lane), which he was unlikely do given Judge Sleet's statements in closing argument suggesting that he found Lane credible over Walters. *Id.* ¶¶ 41-47;[12] *see also* Report of David L. Schwartz (Asimow Decl., Ex. 25 [Dkt. No. 786-13] ¶ 177 (no anticipation because Takeda disclosure does not contain a disclosure regarding the concentration of lidocaine, but merely disclosed ranges).

In their briefs, the parties spend significant time debating whether and how persuasively various arguments were made in the trial court, relying on transcripts as well as Judge Sleet's

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[10] Defendants move to exclude Adelman's testimony. The motion, as discussed below, is DENIED.

[11] Plaintiffs mention in passing that they also rely on Dr. Kishore Shah for anticipation. Shah Report (Sharp Decl., Ex. 14 [Dkt. No. 819-15]) ¶¶ 54-72. However, they do not discuss Shah's opinions in their Opposition. Shah's opinions are likewise the subject of a motion to exclude by defendants, which as discussed below is DENIED.

[12] In closing, Judge Sleet made the following comments:

> . . . I am a jury of one, and in this case, it seems to be not inappropriate for me to take advantage of the opportunity to ask a few questions of counsel.
> It may help me resolve this case.
> So, as you both know, jurors are typically instructed that as the fact-finder, they are free to accept or reject all or any part of any witness' testimony, including that of so-called opinion witnesses or expert witnesses.
> My question is: What result should there be if I largely discount the testimony of Dr. Walters either because of an absence of opinion . . . in critical areas, or because I simply don't find him credible over Dr. Lane?

Asimow Decl., Ex. 5, Closing Arg. Tr. 44. Defendants place much support on these comments as indicating that Judge Sleet intended to find Lane credible over Walters, and given the standard of review on anticipation, the Federal Circuit would have been bound to follow Judge Sleet's acceptance of Lane's opinion there was no anticipation. Defendants read too much into these comments.

comments in closing argument about who he might find credible. However, Judge Sleet had not yet ruled and there was significant, if disputed, evidence in the record to support both sides. Reviewing the record and arguments as a whole, plaintiffs have produced "some" evidence that Watson would have won on anticipation, if not at the district court, then on appeal.

Obviousness

Plaintiffs rely again on Adelman, who opines that even if anticipation was not shown, "the Takeda reference presented a strong case for obviousness, especially when combined with the Teikoku Hydrogel Art and Topical Lidocaine Art." Adelman Report ¶ 108; *see also id*. ¶¶ 39-81.[13] Plaintiffs note that Endo's expert in the '529 trial admitted that the only distinction between the '529 claims and Teikoku's own prior-disclosed hydrogel art was lidocaine, and Watson showed through its expert that Takeda disclosed a lidocaine hydrogel patch that made the '529 claims obvious.[14]

Defendants argue that plaintiffs have failed to adduce evidence that Watson was likely to succeed on both prongs of the obviousness test: to show person of ordinary skill in the art had (a) the motivation to make the invention and (b) a reasonable expectation of success in doing so. Defendants point out at that at trial Endo spent much time arguing through its expert that the art was unpredictable and even Watson's expert had not made a lidocaine hydrogel patch (although he had formulated other lidocaine patches). As to motivation, defendants acknowledge that there was "conflicting testimony" in the trial court, but again rely on Judge Sleet's comments during closing that he would credit Endo's expert over Watson's, and that Endo's expert (Lane) made an extensive argument that prior art "taught away" from putting lidocaine in a hydrogel patch because

[13] Plaintiffs in passing note that they also rely on Shah, who opines that Watson would have won at trial and on appeal on obviousness because, even if not anticipating, the patent was invalid over prior art. Shah Report ¶¶ 73-97. Neither side addresses Shah's opinions in their summary judgment briefing.

[14] Adelman ¶ 84 ("The only conceivable argument against a combination of the Teikoku Hydrogel Art with the Topical Lidocaine Art is that there was no apparent reason to combine lidocaine with a hydrogel patch formulation, but Dr. Lane, Endo's own expert, foreclosed that argument when she admitted that Rowbotham suggests to those of ordinary skill in the art that a patch formulation should be created to better control the rate of administration of lidocaine. Trial Tr. at 996:21-25.").

all prior lidocaine patches were water-free. Closing Argument Tr. at 44.[15]

Reviewing the evidence in *this* record as a whole, plaintiffs have made a strong showing that Watson could have won on obviousness sufficient to defeat defendants' motion for summary judgment.

Unenforceability

Plaintiffs also argue, again relying heavily on Adelman, that Watson was likely to prevail at trial and on appeal because the '529 patent was unenforceable as a result of Teikoku's inequitable conduct. Adelman Report ¶¶ 82-92.[16] The inequitable conduct at issue is whether Teikoku and the '529 inventor (Ono) affirmatively misled the PTO by failing to disclose specific "Teikoku Hydrogel" prior art references. Adelman Report ¶¶ 83-88.

Defendants assert that this defense rises and falls to the same extent as the obviousness defense above, as both rely on the Teikoku Hydrogel prior art. As to intent to deceive, defendants point to Judge Sleet's questions and comments in closing, attempting to distinguish where intent lies when an inventor simply signs whatever disclosures are given to him without review (as Ono testified), and Judge Sleet's comments that he found Ono credible and believed him. Closing Argument Tr. at 45, 108-09. Plaintiffs respond that Judge Sleet's inclinations cannot be deciphered solely from the comments identified by defendants and point out that Judge Sleet also referred to the importance of full disclosure to the PTO from a factual and policy perspective and noted he was free to draw reasonable inferences based on Watson's attempt to show specific intent to deceive. Closing Argument Tr. at 23 105-107.

Plaintiffs also argue that there was sufficient evidence and supporting argument in the record so show that Teikoku engaged in an inequitable "failure to disclose" because the

[15] As noted above, I do not interpret Judge Sleet's questions asking counsel to opine on the impact of his crediting one expert over another as strongly and concretely as defendants do.

[16] As explained by the Federal Circuit, "as a general matter, the materiality required to establish inequitable conduct is but-for materiality. When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291 (Fed. Cir. 2011). There is an exception for but-for materiality, "[w]hen the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material." *Id*. at 1292.

declarations submitted to the PTO asserted only "fictional distinctions" over prior art and its experts (and Watson's at the '529 trial) asserted that the non-disclosure was material and Ono's failure to disclose the prior art was egregious. Defendants respond that because Watson did not assert affirmative misrepresentations (based on omissions) in the '529 trial itself, plaintiffs cannot rely on that theory to show Watson could have won on that ground in this case. However, the evidence underlying this theory is *in* the '529 record and even if not expressly argued at closing, could have formed a basis of either the trial court or Federal Circuit's decisions.

Plaintiffs have presented strong evidence that Watson could have succeeded on unenforceability.

Other Grounds

Defendants argue that in light of an erroneous claim construction by Judge Sleet (as subsequently confirmed by the Federal Circuit in *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350 (Fed. Cir. 2016)), Watson would have lost its appeal on infringement. Plaintiffs do not really dispute this position, although they rely on an expert for the essentially-agreed-to position that Watson would have won on non-infringement at the trial court level. Instead, plaintiffs argue in passing that Endo bears the burden to show infringement on summary judgment *here* – because they bore that burden in the '529 litigation – and they failed to do so. Pls. Oppo. to Defs. MSJ at 22. Defendants dispute this, contending that because it is plaintiffs' burden here to show antitrust injury premised on non-infringement or invalidity, they bear the burden to show non-infringement by Watson. Plaintiffs have *not* introduced "some evidence" that a reasonable juror could rely on to find that Watson would have ultimately won on non-infringement.

Similarly, defendants also move for "summary judgment" on the "derivation defense," arguing plaintiffs cannot establish a genuine issue of material fact that Watson could have proven in the '529 litigation that a third-party conceived of the '529 invention. Defs. MSJ at 12. Plaintiffs do not address this defense in their Opposition.

Accordingly, under Rule 56(g), the material facts that Watson could not have won on non-infringement and derivation are established for trial.

iii. '529 Litigation Record

Plaintiffs also rely on three categories of evidence introduced by Watson in the '529 litigation that a reasonable juror could rely on to determine that Watson would have won at trial and on appeal without regard to plaintiffs' experts' analyses. That evidence concerns: (i) anticipation by Takeda; (ii) obviousness in light of the Teikoku Hydrogel prior art and teachings to use lidocaine in those patches; and (iii) inequitable conduct before the PTO. Pls. Oppo. to Defs. MSJ at16-18. This evidence is the same as that relied upon by its experts above and, as noted, helps plaintiffs meet the "some evidence" mark.[17]

Defendants' motion for summary judgment on the ground that the '529 patent broke the chain of antitrust causation is DENIED.

2. Plaintiffs' Alternative Theory of Causation

Plaintiffs have a second theory of causation; that absent the reverse-payment Settlement, the parties still would have agreed to an anticompetitive settlement, but one where no payment was made and only early generic entry was allowed. Defendants argue that this theory is not legally viable (and move to exclude the expert testimony submitted in support of it). Even if legally viable, defendants argue that it is purely speculative as there is no evidence in the record to support it.

a. Whether the Theory is Cognizable

Defendants argue this alternate theory is not cognizable as a matter of law and (at least with respect to the Cartwright Claims) is barred by the California Supreme Court's decision in *In re Cipro Cases I & II*, 61 Cal. 4th at 153. There, in determining the elements of a prima facie case under the Cartwright Act and who bears the burdens, the court noted that: "Unless a challenged

[17] Plaintiffs also argue, as a fallback position, that defendants failed to produce evidence showing that if Endo/Teikoku won the '529 patent litigation, Endo/Teikoku would have forced Watson off the market. Plaintiffs contend that even if Endo/Teikoku had been successful at trial and on the eventual appeal, an injunction forcing Watson off the market was uncertain as to timing (because when that remedy would have been available depended on what grounds the Federal Circuit decided on and whether judgment was entered by the Circuit or the case was remanded to Judge Sleet) and as to certainty (because Endo/Teikoku could well have determined that Watson's penetration into the market made it more profitable for Endo/Teikoku to allow Watson to continue its sales with royalties). In light of the rulings made above, I need not reach this argument on summary judgment.

settlement agreement includes *both* a restraint on generic competition and a reverse payment to the generic in excess of both brand litigation costs and generic collateral products and services, there is no reason to assume the settlement includes any element of purchased freedom from competition, as opposed to a limit on competition flowing naturally, and lawfully, from the perceived strength of the brand's patent." *Id*. at 153 (emphasis added). The court explained that the relevant "baseline" is the "average period of competition that would have obtained in the absence of settlement." *Id*. at 158.

As plaintiffs point out, however, the *Cipro* court was not analyzing causation – the critical issue here – but whether a Cartwright antitrust claim could be asserted in face of a patent defense, essentially considering the same issue that was before the Supreme Court in *Actavis*. Moreover, the *Cipro* court's comments do not foreclose an argument that antitrust injury could have been nonetheless *caused* in absence of a reverse-payment if there is evidence in the but-for world that the parties would have reached an agreement to drop the patent litigation in exchange for early generic entry into the market.

The district court in *Wellbutrin* recognized the viability of the "alternate settlement" method of proving causation, *In re Wellbutrin XL Antitrust Litig*., 133 F. Supp. 3d 734, 757 & n.2 (E.D. Pa. 2015), but rejected the theory on the facts of that case where there were "no facts in the summary judgment record" to support it. *Id*. at 757. The evidence there was expressly to the contrary; the record was replete with evidence that the generic manufacturer would not settle absent a no authorized generic (AG) agreement. *Id*.[18] On appeal, the Third Circuit agreed that alternate settlement scenarios can support causation, but that evidence was required to support such a theory and it could not rest on "pure speculation." *Wellbutrin*, 868 F.3d at 167 & n.57.

Relatedly, defendants argue that plaintiffs' alternate theory – that some other settlement would have been reached – is an impermissible attempt to show cognizable harm by arguing "that

[18] In rejecting plaintiffs' alternate settlement causation theory, the district court also noted that plaintiffs' expert Leitzinger (who is plaintiffs' expert here) did not explain what the proposed "alternate" settlement would have looked like and rested his testimony solely on fact that their reverse payment was not "justified." *Id*. at 757-58.

the parties might have elected a different settlement agreement more favorable to competition and consumers." *In re Cipro Cases I & II*, 61 Cal. 4th at 150 n.10. But plaintiffs are not attempting to require (or show) that defendants *should have* settled on terms that are the most favorable to consumers. Instead, they are positing an alternative settlement scenario that shows but-for the reverse-payment agreement, the parties would have reached a settlement that was still anti-competitive and caused unjustified harm to consumers.[19]

In addition to *Cipro*, defendants rely on other cases (arising primarily in the legal malpractice context, not in reverse-payment cases) to argue that "alternative settlement" scenarios are generally not cognizable. *See* Defs. MSJ at 26-27. Those cases are inapposite. In the antitrust context, where but-for worlds are considered and profit-maximizing goals assumed, there is by necessity second-guessing involved, although that second-guessing has to be supported by *evidence* as discussed below.[20] A similar concept has been adopted in patent litigation, where reasonable royalties have to be constructed based on hypothetical negotiations. *See, e.g.*, *Fujifilm Corp. v. Motorola Mobility LLC*, No. 12-CV-03587-WHO, 2015 WL 1737951, at *2 (N.D. Cal. Apr. 8, 2015) ("The hypothetical negotiation is a legal construct that 'attempts to ascertain the royalty upon which the parties would have agreed had they successfully negotiated an agreement just before infringement began.'" (quoting *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed.Cir. 2009)).

b. Whether There is Sufficient Evidence to Survive Summary Judgment

Plaintiffs' experts identify various "no payment" settlements providing Watson with early access at different dates that would still have been in defendants' favor and still have caused

[19] Plaintiffs spend significant time arguing that no-payment settlements of Hatch Waxman Act (HWA) patent litigation are common (if not predominant) and arguing that HWA settlements that restrict generic access, even in absence of payments, still have anticompetitive effects. Those points are not in dispute.

[20] As explained by the Ninth Circuit, "[i]n a hypothetical economic construction, such as the one underlying Murphy's theory on lost past profits, economic rationality must be assumed for all competitors, absent the strongest evidence of chronic irrationality. Otherwise it will be impossible to keep speculation in check." *Murphy Tugboat Co. v. Crowley*, 658 F.2d 1256, 1262 (9th Cir. 1981).

plaintiffs injury (*i.e.*, could not be justified by procompetitive reasons); the Retailer Plaintiffs rely on the economic analysis of Dr. Keith B. Leffler and the remaining plaintiffs rely on Professor Einer Elhauge. Elhauge concludes that the hypothetical licensed entry date would have been October 26, 2012. Elhauge Report [Dkt. No. 783-2] ¶ 139. Leffler concludes that January 3, 2013 is the hypothetical early-entry date to which defendants would have agreed. Leffler Report [Dkt. No. 278-2] ¶ 37.

Defendants argue that Elhauge's opinions – based on estimated bargaining strength (tied to the actual Settlement terms) that is then applied to the hypothetical negotiation – are based on unreasonable assumptions about finances and risk. In particular, defendants challenge Elhauge's use of the actual Settlement to estimate bargaining power in a "very different" hypothetical settlement.

Defendants challenge Leffler's different approach – calculating entry dates by valuing the parties' expectation of profits from an early-entry only settlement as opposed to continued litigation – as based only on an inference that otherwise unjustified delay exists from the existence of the unjustified large reverse payment. Such an inference was found to be insufficient in *Wellbutrin*, 133 F. Supp.3d at 757-58.

Finally, defendants challenge both Elhauge's and Leffler's lack of experience with real world negotiations in general and HWA settlement negotiations in particular as grounds to find their testimony speculative and insufficient to support summary judgment.

Plaintiffs respond that Elhauge's analyses are based on the accepted-in-antitrust law proposition that parties are profit-maximizing, meaning that no party would agree to a settlement unless the settlement payoff exceeded its litigation payoff. Starting from this proposition, and using the terms of the Settlement agreed to and the companies' own profit projections, Elhauge calculated that if Endo thought it had more than a 15.1% chance of winning, it would not have rationally agreed to the actual Settlement. Elhauge Report ¶¶ 6, 147. Then he considered the various possible strengths each party could have rationally had with respect to the litigation, to produce a range of feasible no-reverse-payment-settlement early entry dates that still would have provided each party with a payoff exceeding its litigation payoff. Plaintiffs explain that Leffler's

analyses, while different, are also firmly rooted in economic theory and tied to the facts in this case. Leffler used economic literature analyzing settlements, but then also calculated Endo's profits from winning versus losing the patent litigation and weighted those expectations based on the objective expectations provided by Adelman.

Both of these case-based analyses – applying accepted principles in antitrust law and settlement analysis to evidence in this case – are different than what happened in *Wellbutrin*. There, the expert provided no testimony that an alternate settlement would have been reached nor described what that settlement would have looked like. 133 F. Supp. 3d at 757-58. Here, as noted above, both experts' approaches are fully consistent with the principles applied in but-for damage calculations. *See, e.g., Dolphin Tours, Inc. v. Pacifico Creative Serv., Inc.*, 773 F.2d 1506, 1511 (9th Cir. 1985) (plaintiffs "must presume the existence of rational economic behavior in the hypothetical free market."); *see also Murphy Tugboat Co. v. Crowley*, 658 F.2d 1256, 1262 (9th Cir. 1981) ("economic rationality must be assumed for all competitors, absent the strongest evidence of chronic irrationality").[21]

Defendants do not point to any specific evidence considered or assumptions made by the experts that are contrary to evidence in the record. *See, e.g., In re Online DVD-Rental Antitrust Litig.*, 779 F.3d 914, 924 (9th Cir. 2015) ("Subscribers' experts' testimony is contrary to the undisputed market facts."); *Pennsylvania Dental Ass'n v. Med. Serv. Ass'n of Pennsylvania*, 745 F.2d 248, 261 (3d Cir. 1984) (expert affidavit that expressed opinion based on specific factual assertions for which no support was provided, could not defeat summary judgment). At most defendants criticize plaintiffs' experts for failing to consider or adequately consider certain points they believe are significant (*e.g.*, risk adversity); those sorts of disagreements are the subject for

[21] The cases that defendants rely on to argue that economic rationality and profit-maximizing are not appropriate (much less required) assumptions stand at most as criticisms of expert testimony that ignored established facts and market structures and attempted to rely *only* on theories of rationality/profit-maximization. *See, e.g., Am. Booksellers Ass'n, Inc. v. Barnes & Noble, Inc.*, 135 F. Supp. 2d 1031, 1040 (N.D. Cal. 2001); *The Iams Co. v. Nutro Prod., Inc.*, No. 3:00-CV-566, 2004 WL 5496244, at *3 (S.D. Ohio June 30, 2004) (expert could not rely on logical economic rationality assumptions to argue "perfect cross-elasticity of demand" between two brands of dog food where it was "untested by the evidence in this case.").

cross-examination.[22]

Plaintiffs, through their experts, have applied evidence from the record in this case to posit alternative early entry settlement dates in support of their second causation theory. While defendants challenge their methodologies, defendants have not shown that their conclusions are contradicted by undisputed evidence in the record. Defendants' motion for summary judgment on the second causation theory is DENIED.

II. DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT RE CAUSATION/MANUFACTURING

In the alternative, defendants move for partial summary judgment arguing that undisputed evidence demonstrates that Watson could not have launched its generic earlier than December 17, 2012, and defendants' conduct (if anticompetitive) could not have caused plaintiffs any alleged injury before that date. Defs. Mot. for PSJ [Dkt. No. 794].

Plaintiffs do not oppose and do not intend to argue or show that they suffered any injury prior to December 17, 2012. Pls. Oppo. to Mot. for PSJ at 1 [Dkt. No. 814]. Accordingly, I GRANT defendants' partial motion under Rule 56(g) finding that: (i) Watson could not have launched generic Lidoderm any earlier than December 17, 2012, and (ii) defendants' alleged conduct could not have caused plaintiffs injury prior to that date. Dkt. No. 794-21.

Plaintiffs ask me to go further to find that there is no genuine dispute under Rule 56(a) or (g) that: (i) Watson had 23 million patches manufactured by March 26, 2013 in the actual world (*i.e.*, the world with the reverse payments), and thus it would have had at least that many patches by that date in the but-for world (*i.e.*, the hypothetical world absent the delay caused by the reverse payments), and (ii) 23 million patches is what Watson contemporaneously considered to be the number with which it would launch its generic Lidoderm patches. *Id.*

Defendants oppose plaintiffs' request as procedurally improper and also argue that disputes of material fact preclude the findings plaintiffs seek. Defs. Reply ISO MPSJ at 2 [Dkt. No. 850].

[22] Defendants' argument that Elhauge's and Leffler's opinions should be discounted (or excluded) because they are not experts in legal negotiations or negotiations more generally (like defense expert Moffitt), is also unpersuasive, particularly given the profit-maximizing assumption that runs throughout the legal and factual issues to be resolved in this case.

First, defendants argue that there are disputes of fact whether Watson would have manufactured generic Lidoderm in the but-for world at the same rate as it did in the actual world. According to defendants, Watson's manufacturing difficulties required Watson to pause its production of generic Lidoderm in June 2012; after technical and operational fixes, it resumed production in September 2012. Plaintiffs' position is that absent the Settlement, Watson would not have paused to make those fixes and continued production. Defendants respond that even if that is correct, the level of production would have continued to be slow (much slower than it was in the actual world after the fix) and Watson would not have had 23 million patches until July 21, 2013. Amended Expert Report of Benoit Cossart [Dkt. No.794-10] ¶¶ 95-97; *see also* Depo. Tr. of John Spigiel [Dkt. No. 850-4] at 242-243 (production of 23 million patches by March 2013 was due in part to the ability to fix technical issues). The Cossart and Spigiel testimony raise a dispute of material fact precluding a finding under Rule 56(g).

As to the amount of patches Watson wanted to have at launch, 23 million patches (launch quantities plus 4 weeks of inventory) or 35 million patches (launch quantities plus 12 weeks inventory), plaintiffs rely on testimony from Watson's plant General Manager Spigiel that "sufficient quantities" for launch, 23 million patches, were not achieved until March 2013 and that Watson documents show that 23 million patches was the forecasted launch quantity. Pls. Oppo. to Defs. MSJ re Causation at 4-6. Defendants respond that a "typical" launch would have required 12 weeks of supply, relying on the testimony of then-Assistant Director of Materials Lee Lamborn, who also testified that he could not recall a launch where Watson had less product on hand. The documents plaintiffs rely on, according to defendants, address a reduced launch supply and show that the launch target for Lidoderm was a moving target. Again, the differing interpretations of the documents at issue and related testimony raise a material dispute of fact for the jury precluding a finding under Rule 56(g).

Defendants' motion for partial summary judgment on this limited issue is GRANTED and plaintiffs' attempted-cross motion is DENIED.

III. PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT

Plaintiffs move for partial summary judgment seeking to establish: (i) the "contract,

combination, or conspiracy" elements of their Section 1, Section 2, and state law conspiracy to monopolize claims is satisfied by the Agreement; and (ii) the composition of the relevant antitrust product and geographic markets is lidocaine 5% patches (both in branded and generic forms) sold in the United States. In the alternative, plaintiffs move under Rule 56(g) to establish the same facts for trial.

A. Agreement, Conspiracy, or Combination Element

Plaintiffs argue that the Settlement Agreement, signed by all three defendants, satisfies the "contract, combination, or conspiracy" elements of their Section 1, Section 2, and state law conspiracy to monopolize claims. Defendants do not dispute this, although they do dispute the significance, lawfulness, and effect of the various provisions in that Agreement. Def. Oppo. to MSJ [Dkt. No. 812] at 25. Plaintiffs' motion is GRANTED on this issue.

B. Antitrust Product Market[23]

Plaintiffs seek summary judgment defining the relevant antitrust product market as limited to lidocaine 5% patches; in other words, Lidoderm and its generics. Defendants oppose and contend that the market should include a host of other pain medications that come in various forms including nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen and Celebrex, anticonvulsants like Lyrica, antidepressants like Cymbalta, muscle relaxers like Flexeril, opiods like tramadol, and topical anesthetic creams and gels like Qutenza.

Plaintiffs argue that there is no cross-elasticity of demand between Lidoderm and *any* other product (other than generic Lidoderm), and that therefore as a matter of law the relevant market is limited to Lidoderm and its generics. They contend that defendants' experts did not consider the key and necessary legal issue of cross-elasticity of demand at all. Defendants counter that cross-elasticity of demand is relevant but not *required* to determine the relevant product market, and that other considerations – including evidence that other products are therapeutically similar and evidence about non-price competition in the pharmaceutical industry – are relevant to the

[23] The relevant antitrust market includes a geographic market and a product market. *Tanaka v. Univ. of S. California*, 252 F.3d 1059, 1063 (9th Cir. 2001). There is no dispute that the geographic market is the United States.

determination of the product market to be decided by the jury. Even if cross-elasticity is a required element, defendants argue their expert made evidence-based inferences about cross-elasticity that likewise raise material issues of fact precluding summary judgment on the product market definition.

1. In General

"The elements of a cause of action for an unreasonable restraint of trade under the rule of reason analysis" are: "(1) An agreement among two or more persons or distinct business entities; (2) Which is intended to harm or unreasonably restrain competition; (3) And which actually causes injury to competition." *Kaplan v. Burroughs Corp*., 611 F.2d 286, 290–91 (9th Cir. 1979) (citing *Times-Picayune Publishing Co. v. United States*, 345 U.S. 594, 615 (1953)). "Proof that the defendant's activities had an impact upon competition in a relevant market is an absolutely essential element of the rule of reason case." *Id*. at 291. Defining the appropriate market is key because "[i]t is the impact upon competitive conditions in a definable product market which distinguishes the antitrust violation from the ordinary business tort." *Id*.

Determination of the relevant market is typically a fact-intensive inquiry, involving "identification of the field of competition: the group or groups of sellers or producers who have actual or potential ability to deprive each other of significant levels of business. . . . This definitional process is a factual inquiry for the jury; the court may not weigh evidence or judge witness credibility." *Thurman Indus., Inc. v. Pay 'N Pak Stores, Inc*., 875 F.2d 1369, 1374 (9th Cir. 1989).[24] Here, however, plaintiffs contend summary judgment is warranted because defendants cannot show that a material dispute of fact exists on a necessary element; cross-

[24] "In limited settings [ ] the relevant product market may be narrowed beyond the boundaries of physical interchangeability and cross-price elasticity to account for identifiable submarkets or product clusters." *Thurman Indus.* 875 F.2d at 1374. As the Ninth Circuit has explained, "[t]he concept of identifying submarkets for antitrust purposes had its first exposition in *Brown Shoe* . . . . There, the Supreme Court delineated several factors for consideration in the conduct of a submarket inquiry: whether industry or the public recognizes the proposed submarket as a separate economic entity; whether the products involved have peculiar characteristics or uses; whether unique production facilities are involved; and whether distinct customers, distinct prices, price change sensitivity, or specialized vendors highlight the proposed submarket." *Id.* at 1375. The *Brown Shoe* "indicia are practical aids for identifying the areas of actual or potential competition and that their presence or absence does not decide automatically the submarket issue." *Id*.

elasticity of demand between 5% lidocaine patches and the products defendants contend should be included in the relevant market.

2. Cross-Elasticity of Demand

Plaintiffs' motion hinges on the position that cross-elasticity of demand *must* be present between a defendant's product and other products for those other products to be "reasonably interchangeable" and included in the antitrust product market. Cross-elasticity of demand occurs where "an increase in the price of one product leads to an increase in demand for another, both products should be included in the relevant product market." *Olin Corp. v. F.T.C.*, 986 F.2d 1295, 1298 (9th Cir. 1993). "The determination of what constitutes the relevant product market hinges, therefore, on a determination of those products to which consumers will turn, given reasonable variations in price." *Lucas Automotive Engineering, Inc. v. Bridgestone/Firestone, Inc*. (9th Cir. 2001) 275 F.3d 762, 767 (9th Cir. 1997); *see also Forsyth v. Humana, Inc*., 114 F.3d 1467, 1483 (9th Cir. 1997), *aff'd*, 525 U.S. 299 (1999), *overruled on other grounds by Lacey v. Maricopa Cty*., 693 F.3d 896 (9th Cir. 2012) ("A high cross elasticity of demand indicates that products are close substitutes, and should probably be treated as part of the same market. A low or zero cross elasticity of demand is evidence that products do not compete in the same relevant market.").

Numerous cases have recognized the importance of cross-elasticity to determining what products should be included in or excluded from the relevant antitrust market. *See, e.g., Gorlick Distribution Centers, LLC v. Car Sound Exhaust Sys., Inc*., 723 F.3d 1019, 1025 (9th Cir. 2013) ("Instead, products must be reasonably interchangeable, such that there is cross-elasticity of demand." (citing *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962))[25]; *Spindler v. Johnson & Johnson Corp*., No. C 10-01414 JSW, 2011 WL 12557884, at *2 (N.D. Cal. Aug. 1, 2011) ("Using these factors, products may be considered 'reasonably interchangeable,' where there is cross-elasticity of demand, *i.e.* if customers would switch to alternatives in response to a price increase in the alleged monopolist's product." (citing *Rebel Oil, Co. v. Atlantic Richfield Co*., 51 F.3d 1421, 1436 (9th Cir. 1995)); *Pinnacle Sys., Inc. v. XOS Techs., Inc*., No. C-02-03804-

[25] *Gorlick* also recognized, however, that products only need to be reasonably interchangeable, not "perfectly fungible" or physically identical. *Id*. at 1025.

RMW, 2003 WL 21397845, at *7 (N.D. Cal. May 19, 2003) ("'alleged product market must (1) include all products reasonably interchangeable, determination of which requires consideration of cross-elasticity of demand'") (quoting *Intellective, Inc. v. Massachusetts Mut. Life Ins. Co*., 190 F.Supp.2d 600, 609 (S.D.N.Y. 2000)); *see also Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc*., 375 F.3d 1341, 1364 (Fed. Cir. 2004), *rev'd on other grounds by* 546 U.S. 394 (2006) ("Nothing in the record addresses whether potential customers of the patented process faced with a price increase would shift to other processes offering different combinations of benefits. [] This determination, however, lies at the heart of market definition in antitrust analysis."); *Telecor Commc'ns, Inc. v. Sw. Bell Tel. Co*., 305 F.3d 1124, 1131 (10th Cir. 2002) ("The basic relevant product market test is 'reasonable interchangeability.' . . . . Interchangeability may be measured by, and is substantially synonymous with, cross-elasticity."); *United States v. Microsoft Corp*., 253 F.3d 34, 53–54 (D.C. Cir. 2001) ("The test of reasonable interchangeability, however, required the District Court to consider only substitutes that constrain pricing in the reasonably foreseeable future, and only products that can enter the market in a relatively short time can perform this function."); *Brookins v. Int'l Motor Contest Ass'n*, 219 F.3d 849, 854 (8th Cir. 2000) ("But that assertion requires proof there is no cross-elasticity of demand between this game and other games that modified car racers might choose to play."); *Thurman Indus*, 875 F.2d at 1374 ("a product market is typically defined to include the pool of goods or services that qualify as economic substitutes because they enjoy reasonable interchangeability of use and cross-elasticity of demand."); *Oltz v. St. Peter's Cmty. Hosp*., 861 F.2d 1440, 1446 (9th Cir. 1988) ("The product market includes the pool of goods or services that enjoy reasonable interchangeability of use and cross-elasticity of demand."); *Hayden Pub. Co. v. Cox Broad. Corp*., 730 F.2d 64, 70-71 (2d Cir. 1984) ("There is persuasive authority for interpreting *du Pont* as requiring consideration of cross-elasticity of demand in determining an appropriate market definition. . . . We are persuaded that, as a general rule, the process of defining the relevant product market requires consideration of cross-elasticity of demand.").

The Ninth Circuit has specifically acknowledged that "[t]he principle most fundamental to product market definition is 'cross-elasticity of demand' for certain products or services.

Commodities which are 'reasonably interchangeable' for the same or similar uses normally should be included in the same product market for antitrust purposes." *Kaplan*, 611 F.2d at 291. The ABA's Model Jury Instruction in Civil Antitrust Cases (2016) uses the same concept:

> To determine whether products are reasonable substitutes for each other, you must consider whether a small but significant and non-transitory increase in the price of one product would result in enough customers switching from that product to another product such that the price increase would not be profitable. In other words, will customers accept the price increase or will so many switch to alternative products that the price increase will be withdrawn? Generally speaking, a small but significant and non-transitory increase in price is approximately a 5 percent increase in price not due to cost factors [but you may conclude in this case that some other percentage is more applicable to the product at issue]. If you find that customers would switch and that the price increase would not be profitable, then you must conclude that the products are in the product market. If, on the other hand, you find that customers would not switch, then you must conclude that the products are not in the product market.

Instruction 4: Relevant Product Market, Model Jury Instructions in Civil Antitrust Cases ABA (2016) at 108.[26]

Defendants respond that given the unique characteristics of the pharmaceutical market – primarily the prevalence of non-price methods of competition as well as that prescribing physicians do not typically consider price when prescribing drugs – cross-elasticity of demand is not required. Instead, they argue that evidence of reasonable interchangeability (therapeutic equivalency) with other pharmaceutical products used to treat the conditions Lidoderm was prescribed to treat is the more relevant factor that should determine the antitrust product market here.[27]

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[26] *Id*. pg. 109 at n.2 ("In assessing whether products are within the relevant market, the jury must consider not only whether the products are functionally similar but also whether the products are economically interchangeable. That is, there *must* be cross-price elasticity of demand.") (emphasis added).

[27] Defendants do not argue about a submarket, but they rely for support in considering these other factors on the *Brown Shoe* decision, where the Supreme Court recognized that "within this broad market, well-defined submarkets may exist which, in themselves, constitute product markets for antitrust purposes. . . .[citation omitted]. The boundaries of such a submarket may be determined by examining such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." 370 U.S. at 325.

In support, defendants rely on two experts: Dr. Gregory K. Bell and Dr. Christopher J. Gilligan. Gilligan, a pain medicine specialist, provided a report identifying the clinical uses of Lidoderm and products that could be substituted for those clinical uses in place of Lidoderm. Gilligan Report [Dkt. No. 776-32]. Gilligan admits that Lidoderm was approved by the FDA to treat postherpetic neuralgia (PHN), but contends it is also "frequently prescribed" to treat other neuropathic, musculoskeletal and myofascial pain conditions, as well as pain associated with arthritis and other miscellaneous pain conditions. *Id.* ¶ 18. When using Lidoderm to treat musculoskeletal/myofascial pain, Gilligan opines that "physicians will often consider Lidoderm to be interchangeable with the following prescription and over-the-counter ('OTC') medications: lidocaine gel/ointment/cream, topical and systemic non-steroidal anti-inflammatory drugs ('NSAIDs'), acetaminophen, certain opioids and muscle relaxants. *Id.* ¶ 20.[28] When treating pain associated with "arthritis, especially osteoarthritis, physicians consider Lidoderm to be interchangeable with lidocaine gel/ointment/cream, topical NSAIDs, such as Voltaren Gel or Flector Patch, and systemic NSAIDs such as Aleve, Advil or Motrin, Celebrex, and Tylenol." *Id.* ¶ 21. When treating "PHN and other neuropathic pain conditions, physicians may consider Lidoderm to be interchangeable with topical lidocaine gel/ointment/cream, capsaicin creams and patches, systemic nerve pain medications including anticonvulsants (such as Neurontin and Lyrica), antidepressants (such as Nortriptyline, Amitriptyline, and Cymbalta), acetaminophen, and as well as opioids (particularly tramadol)." *Id.* ¶ 22.[29]

Using the information from Gilligan, actual prescription data, and additional other sources showing Lidoderm could be interchanged with other treatments – including clinical guidelines and formulary placements – Bell agreed that Lidoderm was not only used to treat PHN but also used

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[28] Gilligan believes that Lidoderm is most often prescribed to treat musculoskeletal/myofascial pain. *Id.* ¶ 25. Bell concurs. Bell Report ¶ 46 (finding 57% of Lidoderm prescriptions were for musculoskeletal pain).

[29] Gilligan defines "interchangeable" as "that a treating clinician considers these treatments to be therapeutically equivalent: their relative risks and benefits are such that they are frequently substituted for each other depending on the patient's specific circumstances. This does not mean that the treatments are identical in other respects, such as their formulation, mechanism of action, method of application, or risks and benefits for particular patients." *Id.* ¶ 17.

"extensively" to treat other forms of neuropathic pain, pain from arthritis, and musculoskeletal pain. Bell Report [Dkt. No. 776-8] ¶ 6.[30] As a result, according to Bell and defendants, the relevant antitrust product market includes "the primary competitors from each of these four categories of significant Lidoderm use." *Id*. Those "primary competitors" include, "at least the following: the opioid Ultram (tramadol); the anticonvulsants Neurontin (gabapentin) and Lyrica (pregabalin); the antidepressant Cymbalta (duloxetine); the muscle relaxant Flexeril (cyclobenzaprine); the nonsteroidal anti-inflammatory drugs ("NSAIDs") Celebrex (celecoxib), diclofenac (including Voltaren Gel), ibuprofen, Mobic (meloxicam), and naproxen; and the topical anesthetics capsaicin (Qutenza and Zostrix) and lidocaine (including cream, gel, and ointment formulations)." *Id*. Based on his review of evidence, Bell concluded that "Lidoderm's share of prescriptions among these products from 2011 through 2014 is 13 percent for PHN and no more than two percent otherwise." *Id*. ¶ 83.[31]

In support of this broad market definition, defendants also rely on Endo documents showing how Lidoderm was marketed and promoted with managed care organizations (MCOs) and healthcare organizations as well as doctors. Those documents show that Endo made efforts to convince physicians to prescribe Lidoderm over other the other drugs, including Neurontin, Lyrica, capsaicin, topical aspirin formulations, lidocaine gel, and Qutenza. Asimow Decl. [Dkt. No. 812-1] Ex. 6, at ENDO-LID-AT-000967095 (identifying the competitive marketplace for PHN treatments). Finally, defendants also note that Endo monitored Lidoderm prescriptions and market share compared to Lyrica, branded and generic Neurontin, and Qutenza Asimow Decl. Ex. 3, at slides 9-14.

[30] As part of his analysis, Bell opined that "off label" use of Lidoderm accounts for 92% of prescriptions. *Id*. ¶¶ 46, 64. As discussed below, if plaintiffs' motion for partial summary judgment as to the market definition is not granted, plaintiffs' move to exclude the testimony of Dr. Bell.

[31] In defining the market, Bell also examined evidence regarding the prevalence of non-price competition in the pharmaceutical market, concluding that "competitive constraints on Endo" required Endo to give significant rebates and other price concessions to MCOs and used free samples and other marketing efforts to encourage health care organizations and doctors to prescribe Lidoderm. *Id*. ¶¶ 70-76.

Defendants' analysis – essentially ignoring cross-elasticity – creates a vastly overbroad market that includes a host of different classes and types of drugs that are different from the "unique" 5% lidocaine patches. As the Supreme Court has cautioned: "For every product, substitutes exist. But a relevant market cannot meaningfully encompass that infinite range. The circle must be drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn; in technical terms, products whose 'cross-elasticities of demand' are small."[32] *Times-Picayune Pub. Co. v. United States*, 345 U.S. 594, 612 (1953).

Indeed, even where products are essentially identical, that alone is insufficient to require their inclusion in the relevant market. *See, e.g., U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 996 (11th Cir. 1993) (excluding from the market functionally similar products where the "record provides no support for finding significant cross-elasticity of demand or supply between Danforths and generic anchors"); *United States v. Archer–Daniels–Midland Comp*., 866 F.2d 242, 248 (8th Cir.1988) (functionally interchangeable sweeteners were separate product markets because "a small change in the price of [one] would have little or no effect on the demand for [the other]");[33] *cf. In re Loestrin 24 Fe Antitrust Litig.*, No. 1:13-MD-2472-S-PAS, 2017 WL 3600938, at *12 (D.R.I. Aug. 8, 2017) ("Products are not reasonably interchangeable merely because they share similar forms or functions, but rather '[s]uch limits are drawn according to the cross-elasticity of demand for the product in question—the extent to which purchasers will accept substitute products in instances of price fluctuation and other changes.'" (quoting *In re Nexium*

[32] The Court went onto note also that "[u]seful to that determination is, among other things, the trade's own characterization of the products involved." *Id*.

[33] Defendants argue that the Eighth Circuit's emphasis on lack of cross-elasticity in *Archer Daniels Midland* (*ADM*) was limited by *HDC Med., Inc. v. Minntech Corp*., 474 F.3d 543, 548 (8th Cir. 2007). But any limitation was on a different proposition. *HDC* simply recognized that *ADM* itself recognized a "narrow exception to the general prohibition against placing great weight on *only* price differentials" in determining whether products reside in the same market, in situations where government price support props up one product's price. *Id*. at 548 (emphasis added). Plaintiffs here are not arguing that mere price differentials between Lidoderm and the generics ultimately introduced is evidence of *the market definition*. Defendants' reliance on *In re Remeron Direct Purchaser Antitrust Litig*., 367 F. Supp. 2d 675, 681 (D.N.J. 2005), where plaintiffs did exactly that, is similarly misplaced.

(Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 387–88 (D. Mass. 2013)); *F.T.C. v. Swedish Match*, 131 F. Supp. 2d 151, 158 (D.D.C. 2000) ("while loose leaf and moist snuff tobacco are not identical, in light of substantial similarities between them and in light of the rising trend in dual usage by consumers, the Court ultimately finds the products to be functionally interchangeable for the purpose of outlining the relevant product market. Finding two products to be functionally interchangeable, however, does not end the analysis" and rejecting inclusion in same market where no evidence of cross-elasticity of demand).

Defendants point to no cases arising in the pharmaceutical context where courts (or juries) have defined the relevant product market as broadly as they seek here. Indeed, in the pharmaceutical context courts have limited the market to similar classes of drugs or even more narrowly, down to the brand product itself in absence of cross-elasticity evidence. *See, e.g.*, *SmithKline Corp. v. Eli Lilly & Co*., 575 F.2d 1056, 1064 (3d Cir. 1978) (despite a certain degree of functional interchangeability among antibiotics, specific class of antibiotics was separate product market based on court's finding that there was a lack of price sensitivity and cross-elasticity of demand); *see also F.T.C. v. Lundbeck, Inc*., 650 F.3d 1236, 1240 (8th Cir. 2011) (affirming decision to exclude from relevant market two functionally similar drugs because of lack of cross-elasticity of demand; "When the case was tried, Indocin IV and NeoProfen were the two drug treatments available for PDA. Aware of the drug options—the 'practicable alternatives'—the neonatologists preferred one treatment or the other (without regard for cost), which the court credited as persuasive evidence of low cross-elasticity.");[34] *Geneva Pharm. Tech. Corp. v. Barr Labs. Inc*., 386 F.3d 485, 496 (2d Cir. 2004) (bioequivalent, functionally-interchangeable branded and generic drugs were in separate product markets); *see also In re Lorazepam & Clorazepate*

[34] Defendants point out that in a concurrence Judge Kopf found it odd "to define a product market based upon the actions of actors who eschew rational economic considerations" because doctors paid no mind to price, and that "oddity seems especially strange where, as here, there is no real dispute that (1) both drugs are effective when used to treat the illness about which the doctors testified and (2) internal records from the defendant raise an odor of predation." *F.T.C. v. Lundbeck, Inc*., 650 F.3d at 1243. The facts are different here where no one is contending there is a drug that was identical to Lidoderm (delivering lidocaine in a topical patch) on the market during the relevant time (although topical lidocaine cream was on the market).

Antitrust Litig., 467 F. Supp. 2d 74, 82 (D.D.C. 2006) (reasonable jury could conclude that the relevant antitrust market was comprised of only generic manufacturers where trial testimony was that generic manufacturers did not consider brand price in setting their own prices, both sides' experts testified that generics competed in a different market than the branded manufacturers, and where evidence was that brand and generic drugs had different consumer bases and were promoted and marketed differently).

Defendants' heavy reliance on *Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co*., 838 F.3d 421, 436 (3d Cir. 2016) is misplaced. There, the Third Circuit approved the district court's extensive focus on product interchangeability and refusal to limit the at issue market to just one oral tetracycline and its generic and instead approved a much broader market consisting of "all oral tetracyclines prescribed to treat acne." *Id*. at 436.[35] But the court's analysis did not end there. It noted that "[i]nterchangeability is only one aspect of establishing a relevant antitrust market through indirect evidence," and that the evidence of cross-elasticity of demand between Doryx and other tetracyclines supported the broader adopted market definition. *Id*. at 437.[36]

Consistent with the bulk of the case law, something *more* than mere therapeutic equivalency is required to define the relevant antitrust product market. There must be some showing of cross-elasticity. This conclusion is supported by the undisputed facts in this case:

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[35] Part of that analysis included reliance on the FDA's approval of "virtually identical" labeling for the products that treat the same condition, as well as evidence that managed care providers encouraged the widespread substitution of numerous other oral tetracyclines for Doryx; showings that are absent here. *Mylan*, 838 F.3d at 436.

[36] Defendants also rely on *Bayer Schering Pharma AG v. Sandoz, Inc*., 813 F. Supp. 2d 569 (S.D.N.Y. 2011). There, however, the court rejected the proposed narrowly limited market (two brand and two generic drugs that were a combined oral contraceptive and medication to treat premenstrual dysphoric disorder) as implausible given the multitude of other functionally and chemically similar drugs on the market designed to treat the same symptoms. That the court recognized in those circumstances that the application of cross-elasticity of demand was "complicated given that (1) patient choice is constrained by the physician's prescribing authority, and (2) the impact of price variation may be blunted by the effect of health insurance," is not surprising. *Id*. at 578. Similarly, defendants' reliance on *Kaiser Found. v. Abbott Labs*., No. CV02-2443-JFWFMOX, 2009 WL 3877513, at *8 (C.D. Cal. Oct. 8, 2009) is misplaced. There, essentially identical drugs (alpha-blockers) were reasonably interchangeable, yet plaintiff's expert excluded them from the market for the sole and erroneous reason that those drugs were not "comparable therapeutic substitutes."

Endo and Teikoku have repeatedly characterized Lidoderm as a unique product with unique advantages. *See, e.g.*, Asimow Decl., Ex. 6, at ENDO-LID-AT-000967095 ("LIDODERM is the first and only lidocaine-based topical medication with FDA approved indication for the treatment of PHN pain. Furthermore by minimizing systemic exposure topical lidocaine reduces the risk of systemic side effects."). In the underlying '529 Patent litigation Edgar Ross, M.D. opined on behalf of Endo and Teikoku that Lidoderm was unique: "[Lidoderm] was a unique drug and delivery system combination. . . ." Kohn Decl. [Dkt. No. 776], Ex. DD at ¶¶ 2-4; *see also id*. at ¶ 9 ("there are no satisfactory substitutes for Lidoderm as a highly safe, effective, and convenient topical treatment for neuropathic pain. . . . [T]he unique benefits of LIDODERM's patch formulation have made it highly successful in the treatment of PHN and other types of pain."). Brian Lortie, Endo's President of Branded Pharmaceuticals Business, testified to the FTC that "Lidoderm was unique in the attributes that it presents to a physician and to a patient as they're seeking a therapy for which they are considering products. It's the only topical patch, for example. . . . So there really is not another product that is exactly like Lidoderm. . . . Lidoderm is really a unique product." Kohn Decl., Ex. EE at ENDO-LID-AT-000005144-46; *see also id*. at ENDO-LID-AT-000005148 ("Lidoderm really had a distinct positioning in [physicians'] minds.").[37]

The market for determining monopoly power cannot be stretched as far as defendants seek. This is why numerous courts *have* required some showing of cross-elasticity of demand between products before including them in the same market. Defendants' argument loses focus on the question at hand, which is defining the appropriate market to determine defendants' power to engage in monopolistic behavior.

Defendants argue that instead of cross-elasticity (following a showing of therapeutic equivalency), the jury is entitled to rely on the practical indicia the Supreme Court identified in *Brown Shoe* for identifying submarkets. Def. Oppo. to Pls. MPSJ at 7.[38] Putting aside the fact

[37] The differences between Lidoderm and some of the other drugs that Gilligan and Bell assume are equivalent (*e.g.*, ibuprofen) is obvious even without expert testimony.

[38] Defendants cite one case where cross-elasticity was explicitly not required, primarily because that analysis was not feasible. *See Nobody in Particular Presents, Inc. v. Clear Channel Commc'ns, Inc*., 311 F. Supp. 2d 1048, 1082 (D. Colo. 2004) ("whether reasonable

that defendants have not identified a submarket, but instead argue for a broad initial market, these practical indicia do not support defendants. The "fact-intensive" practical indicia recognized by *Brown Shoe* (and subsequent Ninth Circuit cases) – the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors – support limiting the relevant antitrust market here to Lidoderm and its generics. *Brown Shoe Co.*, 370 U.S. at 325. There is no dispute that during the relevant time, Lidoderm was the only hydrogel 5% lidocaine patch on the market, and the evidence readily shows (without dispute) that Lidoderm required distinct production facilities and capabilities, had distinct prices that were not set with respect to any other drug, and employed specialized sales channels.[39]

The only "practical indicia" relied on by defendants is the evidence that *generally* in the pharmaceutical market, competition occurs on non-price fronts in order to get physicians to prescribe and MCOs and pharmacy benefit managers (PBMs) to cover and include specific drugs in their formularies. As a result, Endo heavily marketed its products to physicians (including extensive use of free samples) and used rebates and other price concessions with MCOs and PBMs to encourage adoption and inclusion of Lidoderm. Defendants cite evidence that Endo consistently tracked its sales/prescriptions of Lidoderm in comparison with therapeutically similar products, primarily anticonvulsants (like Lyrica) and the Qutenza (capsaicin) patch. But defendants do not show that the availability of those other products *forced* Endo to limit its Lidoderm price or otherwise constrained Endo's pricing. That Endo has evidence that physicians

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interchangeability can be determined for antitrust purposes without economic analysis of cross-elasticity of demand. Although the Tenth Circuit has not addressed this specific issue, . . . the court finds that a plaintiff may, through sufficient evidence of other indicia of market definition, define a relevant market without economic study of cross-elasticity of demand, especially when economic analysis of cross-elasticity of demand is infeasible based on pricing data."). As discussed below, there is no evidence that an economic analysis of cross-elasticity of demand was infeasible, but only that defendants did not seek the data to do it.

[39] Plaintiffs rely on these "practical indicia" to support their argument that the market should include only Lidoderm and its generics, focusing on Endo and Teikoku's representations to the market and to the FTC about the "uniqueness" of Lidoderm as the only lidocaine hydrogel patch on the market. *See supra*.

and MCOs were concerned about the "high" price of Lidoderm and prescribed more or made more available where prices were lower or significant rebates were provided does not mean that the *other* products on the market for treatment of PHN and other pain conditions constrained the price of Lidoderm. It simply shows that, in order to grow the market for what defendants repeatedly characterize as a unique product, price concessions and rebates for Lidoderm were necessary.

3. Evidence of Lack of Cross-Elasticity

Plaintiffs rely on their experts' analyses that conclude that there is no evidence of any significant cross-elasticity of demand between Lidoderm and other pharmaceuticals. For example, Dr. Jeffrey J. Leitzinger opines, based on Endo and Teikoku's own documents and testimony, that there is little cross-elasticity between Lidoderm and other pain treatments, with the exception of generic Lidoderm. Kohn Decl., Ex. C, Leitzinger Report [Dkt. No. 776-3] at ¶¶ 44-51. He also relies on an analysis of the price differential between brand Lidoderm (when no generic was on the market) and brand Lidoderm (when generics entered). *Id.* ¶¶ 57-67 (no product other than generic Lidoderm exhibited substantial cross-elasticity of demand with Lidoderm). Dr. Hal J. Singer reviewed price data of Lidoderm, as compared to that of seven PHN treatment drugs that Endo identified as "competitors," and concluded that sales of the competitor drugs were unfazed by changes in the relative price of Lidoderm. Kohn Decl., Ex. D, Singer Report [Dkt. No. 776-4] at ¶¶ 47-51.

Dr. Keith Leffler opines, based again on Endo's own internal documents and projections as well as on his review of sales and price data, that other products used to treat PHN do not have high cross elasticities of demand with Lidoderm. Kohn Decl., Ex. E, Leffler Report [Dkt. No. 776-5] at ¶¶ 27-46. Dr. Glenn Melnick opines that the unique method of administration (transdermal patch) distinguishes Lidoderm from other PHN treatments and that Endo's ability to maintain "inflated" prices demonstrates that there are no constraints on the price of Lidoderm from other products. Kohn Decl., Ex. F, Melnick Report [Dkt. No. 776-6] at ¶¶ 88-91. Finally, plaintiffs also rely on Endo's own evidence and testimony that Endo did not forecast or expect that wholesale acquisition cost (WAC) price increases would result in Endo losing sales to other drugs. *See, e.g.*, Kohn Decl., Ex. I, Depo. Tr. Brian Lortie [Dkt. No. 776-9] at 254; Kohn Decl., Ex. N,

Depo. Tr. Andrew Gesek [Dkt. No. 776-14] at 194.

If evidence on price competition is required, defendants argue that they have it. Bell analyzed Lidoderm's "own price elasticities" to show that when rebates to MCOs/PBMs decreased, utilization decreased and vice-versa. Bell Report ¶¶ 71-74. Plaintiffs respond that evidence of one's "own price elasticities" is not sufficient to allow inclusion of *other*, uncompared-on-price products in the relevant antitrust product market. For example, that Endo increased its price concessions to MCO's from 2008 through 2013 (before generic entry) does not necessarily show that Endo was in price competition with other drugs. It could equally reflect that Endo decided to provide rebates in order to encourage MCOs to continue to provide access (or preferred access) to Lidoderm in their formularies and to increase profits by taking measures to increase the ultimate number of prescriptions by providing larger rebates to MCOs.[40]

Defendants then challenge plaintiffs' experts' evidence on lack of cross-elasticity as deficient and argue that it cannot support summary judgment. The primary deficiency identified by defendants is that plaintiffs' experts – particularly Singer – relied on wholesale acquisition cost (WAC or list price) as opposed to net price (after rebates or other incentives). Defs. Oppo. to Pls. MPSJ at 21-24. Defendants contend that net prices are what matters, given the significant level of rebates and other incentives provided to MCOs. Bell Report ¶¶ 88, 98. Plaintiffs respond that Singer testified that at least for Lidoderm, increases in the WAC closely correlated with changes in net price. As a result, his use of WAC does not undermine his analysis. Asimow Decl., Ex. 8 (Singer Depo. Tr.) at 675:20-676:10.[41] In contrast, defendants' expert Bell asserted only "that

[40] Defendants appear to argue that Bell did not need to conduct an economic analysis of cross-elasticity of demand because Bell did not have access to the data to do so. Def. Oppo to Pl. MSJ at 19-20. However, defendants do not argue or show that the data to enable Bell to perform a net price comparison between Lidoderm and other drugs they contend should be in the same market was unavailable. They contend only that Bell did not have access to it. Plaintiffs respond that the relevant data could have been secured through discovery subpoenas if defendants had wanted to counter plaintiffs' showing. Reply at 9 n.4.

[41] Defendants do not point any evidence, by Bell or otherwise, that increases in the WAC did not generally correlate to increases in the net prices for Lidoderm. Instead, defendants note that Bell, when using net prices, concluded that the price increases for Lidoderm between May 2012 and September 2013 were not *as high* percentage-wise as plaintiffs contended. Defs. Oppo. to Pls. MPSJ at 22 n.10. They do not dispute net percentage increases occurred.

growth in gross sales of Lidoderm outpaced the growth in net sales, indicating that gross prices grew faster than net price." Bell Report ¶ 88. While Bell criticized Singer's (and plaintiffs' other experts') reliance on WAC, Bell did not indicate or offer an analysis on how large the purported gap between those two was or address in substance Singer's analysis that changes in the gross and net prices were largely correlated. Bell Report ¶ 88.

In sum, plaintiffs present evidence that price data and sales data show that during the relevant time there was no significant cross-elasticity of demand between Lidoderm and any product other than generic Lidoderm. Those analyses are generally supported by defendants own documents and analyses. Defendants show, at most, an issue regarding Lidoderm's *market share* for PHN and pain treatment with respect to only a few of the drugs defendants believe should be included in the relevant antitrust market (and at most a limited concern over the price of Lidoderm with respect to the 2010 entry of one drug, Qutenza), but those discrete references are insufficient to raise a material question of fact on whether the availability of those drugs *constrained* the price charged for Lidoderm.

4. The Relevant Market

For the foregoing reasons, based on undisputed facts and total lack of evidence to show that Lidoderm's prices were constrained by therapeutically equivalent products, I conclude as a matter of law that the market is limited to 5% lidocaine patches, Lidoderm and its generic equivalents. Plaintiffs' motion for partial summary judgment in this issue is GRANTED.

IV. MOTIONS IN LIMINE

A. Legal Standard

Federal Rule of Evidence 702 allows a qualified expert to testify "in the form of an opinion or otherwise" where:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and

> (d) the expert has reliably applied the principles and methods to the facts of the case.
>
> Fed. R. Evid. 702.

Expert testimony is admissible under Rule 702 if it is both relevant and reliable. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). "[R]elevance means that the evidence will assist the trier of fact to understand or determine a fact in issue." *Cooper v. Brown*, 510 F.3d 870, 942 (9th Cir. 2007); *see also Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010) ("The requirement that the opinion testimony assist the trier of fact goes primarily to relevance.") (internal quotation marks omitted).

Under the reliability requirement, the expert testimony must "ha[ve] a reliable basis in the knowledge and experience of the relevant discipline." *Primiano*, 598 F.3d at 565. To ensure reliability, the court must "assess the [expert's] reasoning or methodology, using as appropriate such criteria as testability, publication in peer reviewed literature, and general acceptance." *Id.* at 564. These factors are "helpful, not definitive," and a court has discretion to decide how to test reliability "based on the particular circumstances of the particular case." *Id.* (internal quotation marks and footnotes omitted). "When evaluating specialized or technical expert opinion testimony, the relevant reliability concerns may focus upon personal knowledge or experience." *United States v. Sandoval-Mendoza*, 472 F.3d 645, 655 (9th Cir. 2006).

The inquiry into the admissibility of expert testimony is "a flexible one" where "[s]haky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion." *Primiano*, 598 F.3d at 564. "When the methodology is sound, and the evidence relied upon sufficiently related to the case at hand, disputes about the degree of relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 852 (Fed. Cir. 2010). The burden is on the proponent of the expert testimony to show, by a preponderance of the evidence, that the admissibility requirements are satisfied. *Lust By & Through Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996); *see also* Fed. R. Evid. 702 Advisory Cttee. Notes.

B. Plaintiffs' Motions

1. Motion to Exclude in Part Bell

If plaintiffs' motion for partial summary judgment as to the definition of the relevant antitrust product market is denied, plaintiffs move to exclude the testimony regarding that market by defendants' expert Dr. Gregory K. Bell. Dkt. No. 778. However, as noted above, plaintiffs' motion is granted, thereby making moot Bell's testimony regarding the market definition and his criticisms of plaintiffs' experts' testimony relevant to price-elasticity and market definition. Other portions of Bell's testimony may still be relevant to issues to be decided at trial. What, if any, remaining issues Bell may address at trial can be determined on a motion in limine prior to trial.

2. Motion to Exclude in Part Carlton

Plaintiffs move to exclude in the testimony of Dr. Dennis Carlton, to the extent of his testimony regarding: (a) the possibility that after losing the patent trial against Watson, Endo might be able to obtain an injunction against Watson before any appellate ruling; and (b) whether and/or how *F.T.C. v. Actavis, Inc*., 133 S. Ct. 2223 (2013) should be applied to the facts of this case. As to the first issue, plaintiffs argue that Carlton, as an economist, is not qualified to opine on whether had Watson won at trial (which both sides agree was the likely outcome), Endo/Teikoku could nevertheless have secured an injunction preventing Watson from entering the market. As to the second issue, plaintiffs argue that Carlton's opinion – that the inferences and burdens created by the Supreme Court in *F.T.C. v. Actavis, Inc*., 133 S. Ct. 2223 (2013) should not apply in this case because in his view a cash payment (like the one in *Actavis*) is competitively different than the $96 million worth of free branded Lidoderm that Endo gave to Watson – should be excluded because that is an impermissible legal conclusion and outside the realm of his expertise in economics.

Defendants respond that the "testimony" plaintiffs seek to exclude are not Carlton's central opinions. Carlton's central opinions are that: (i) accounting for the projected royalties associated with the no-AG clause, the clause is more rationally viewed as a payment from Watson, rather than a payment to Watson; (2) the settlement inventory had procompetitive features ignored by plaintiffs' experts because it "allowed Watson to compete in those situations where it would not

have been able to otherwise" due to lack of FDA approval; and, in any event, (3) the settlement did not delay generic entry or otherwise harm competition relative to expected outcomes from continued patent litigation. Carlton Report, Asimow Decl., Ex. 4 [Dkt. No. 807-4] ¶¶ 46, 77, 94. As to the first issue identified by plaintiffs, defendants argue that the testimony plaintiffs are concerned with arose in Carlton's deposition where he described his opinions as "conservative" because they did not rely on Endo seeking and securing an injunction and because Carlton did nothing more than identify an injunction pending appeal as one possible factor but one he did not rely on in reaching his "conservative" opinion. As to the second issue, defendants characterize plaintiffs' concern as being one over deposition testimony they elicited but not part of Carlton's opinions. That said, defendants argue that because plaintiffs' experts testify that it is of no consequence as an economic matter that the free products and no-AG-competition provisions provided were "not payments," Carlton should be able to dispute that by arguing that the non-cash "payments" here were "competitively different" from an exchange of cash. Carlton Oppo. at 6.

The issue of an injunction is not central to Carlton's opinions and so plaintiffs' motion is DENIED, subject to renewal at trial if Carlton's testimony ventures into whether an injunction was possible or expected. On the purported significance between cash payments and other types of payments, the motion is GRANTED in part. *No expert* may opine that there is a legal significance to cash versus non-cash payments in reverse payment settlements. However, the expert economists can discuss any differences that various types of payments had or have on competition.

3. EPPs' Motion to Exclude Fritz

The EPPs renew their motion from class certification to exclude the opinion of John Fritz that health insurer members of the EPP class have not suffered any economic harm due to delayed-entry of a generic alternative for brand Lidoderm because any overcharges were passed on. Dkt. No. 769. The EPPs argue, again, that Fritz is not qualified to offer that opinion based on his general actuarial experience (a) because he lacks knowledge of how insurers set premiums or actual practices with respect to Lidoderm and (b) his opinion is based on the experience of one opt-out plaintiff (GEHA) and were not validated to any of the actual class members. The EPPs point out that I denied premium-related pass on discovery in April 2016, because there was, at that

juncture, no evidence that any plaintiff insurer had been able to "recoup" amounts spent in the past on prescription drugs when setting employer contribution rates for the future. April 5, 2016 Minutes.

However, in ruling on the motions for class certification, I denied the motion to exclude Fritz, concluding:

> The weight to be given Fritz's opinion (based on his experience, or lack thereof, and based on the information he did or did not review) is more appropriately challenged at summary judgment or trial. Moreover, while the relevance of Fritz's opinion has not been fully briefed or finally determined (although I have expressed skepticism that the "pass-on" defense will be allowed in this case at least with respect to the federal claims), as explained above the opinion is not persuasive in my determination of the EPPs' certification motion.

February 2017 Class Certification Order at 51-52.

Defendants rely on the fact that I did not exclude Fritz at the class certification stage and contend no new challenges to his testimony have been adduced by plaintiffs. Defendants also argue, again, that pass-on is a defense to many of the EPPs' state law claims. Fritz Oppo. [Dkt. No. 804].

I DENY the motion to exclude. Fritz has actuarial experience and understanding of how, at least in some instances, insurers negotiate and set premiums. Any deficiencies or weaknesses in his testimony based on a lack of facts or experience pertaining to how the EPPs in this case actually set premiums can be fully explored at trial. I will, however, accept a jury instruction to expressly limit any pass-on defense to the applicable state law claims. Plaintiffs are correct that defendants have not, at this juncture, shown that any type of pass-on defense is applicable to the direct purchaser federal claims.

4. Motion to Exclude in Part Moffitt

Plaintiffs move to exclude the testimony of Professor Michael Moffitt to the extent Moffitt proffers testimony to the effect that in the "but-for world," defendants might behave economically irrationally in negotiating a patent settlement without a large reverse payment. Moffitt Mot. [Dkt. No. 771]. Plaintiffs contend that Moffitt's testimony about negotiator irrationality (*e.g.*, that sometimes negotiators act irrationally and against their economic interests) creates a danger of unfair prejudice and is contrary to antitrust law's presumption that firms act rationally. Plaintiffs

point to Moffitt's opinion that economically rational settlements might not be reached where: parties might hold unrealistic views of the strengths of their case (Moffitt Report [Dkt. 771-8] at ¶¶ 66(a), (b)); "might fear to signal agreement" out of reputational concerns (*id*. ¶ 66(c)); might adopt a stubborn, "take-it-or-leave-it" approach (*id*. ¶ 66(d)); or might reject reasonable offers for a variety of other "psychological reasons." *Id*. ¶ 10. Plaintiffs assert that testimony about these "human factors" are improper in a trial where participants must be assumed to be rational profit-maximizers.

Defendants counter that since plaintiffs are contending (under their disputed second causation theory) that defendants would have negotiated a hypothetical settlement that bears little resemblance to the actual Settlement, they are entitled to rely on Moffitt. Defendants also challenge plaintiffs' characterization of Moffitt's testimony, arguing that he does not in fact testify that the parties would have acted in an economically irrational manner but that there are several evidentiary-based reasons why parties may never reach an agreement.

A few initial points bear emphasis. As plaintiffs clarified at the hearing, they only seek to exclude testimony from Moffitt that the parties might have acted in an economically irrational way, as that runs against the presumption in antitrust cases – including those underlying but-for analyses – that economic actors act in economically rational and profit maximizing ways. Hearing Tr. at 96:2-6. Moffitt's testimony concerns two broad areas: first, what factors would have gone into determining whether there was a "zone of possible agreement" (ZOPA) between Endo/Teikoku and Watson and if the negotiation history and other facts show a ZOPA existed does that "necessarily demonstrate that real-world negotiators" could have reached a settlement; and, second, if the settlement negotiations were restricted to entry date only (plaintiffs' alternative but-for scenario), would a settlement have occurred and (if so) could an alternate start date be reasonably determined. Moffitt Report ¶ 2.

I agree with plaintiffs that in the experts' competing testimony about the but-for world, only opinions that are economically rational may be provided.[42] Factors that are economically

[42] As noted above, in construction but-for world scenarios, there is a presumption of economical rationality. *See, e.g., Dolphin Tours, Inc. v. Pacifico Creative Serv., Inc.*, 773 F.2d 1506, 1511

rational (*e.g.*, consideration of the impact of a potential settlement on other or future litigation) are admissible. So is testimony that access to imperfect information or overconfidence based on that imperfect information (as opposed to irrationality) can impact settlements or willingness to enter settlements. *See, e.g.*, Moffitt Rep. ¶¶ 66a. I am not aware of cases showing that these well-known imperfections and hurdles in the settlement process suffered by economically rational actors are impermissible considerations in constructing but-for worlds; therefore, that testimony is permissible. But to the extent that Moffitt or any expert intends to opine that even though other economically rational settlements could have been reached, economically irrational factors (*e.g.*, a general but irrational reticence to settle) would have foundered any settlement, that testimony will not be admissible.

I recognize that this ruling does not lead to a clean segregation of what is impermissible and excludable in Moffitt's report and testimony. Plaintiffs themselves, although moving to exclude in part, have not identified which specific portions of the Moffitt Report that they seek to exclude by line or paragraph number. *See* Dkt. No. 771-10 (Proposed Order). In advance of the pretrial conference, the parties should attempt to agree on the topics to which experts will not be allowed to testify with respect to the theoretical but-for settlement proposed by plaintiffs consistent with this Order, and submit any disputed issues for my determination.

5. Motion to Exclude Murthy

Plaintiffs seek to exclude the opinion of Mr. Harsha Murthy, offered by defendants as an expert on pharmaceutical company decision-making relating to "at-risk" and authorized generic launches – that "it is very unlikely that a company in Watson's position would have launched a generic version" of Lidoderm at-risk because Murthy made "no effort to examine the facts in this case specifically or in the generic drug industry generally to determine what a reasonable company would do here, rendering his opinion wholly speculative and thus unreliable." Murthy Mot. at 1

(9th Cir. 1985) (plaintiffs "must presume the existence of rational economic behavior in the hypothetical free market."); *see also Murphy Tugboat Co. v. Crowley*, 658 F.2d 1256, 1262 (9th Cir. 1981) ("economic rationality must be assumed for all competitors, absent the strongest evidence of chronic irrationality").

[Dkt. No. 773].[43] Plaintiffs criticize Murthy's opinions as "speculative" and not based on any specifically cited evidence in the record of this case or "industry related data."

Defendants oppose, arguing that in accordance with my prior ruling regarding objective expert testimony, Murthy draws on his experiences to explain: (i) what factors a reasonable pharmaceutical executive considers when deciding whether to launch a product "at-risk," (ii) why a reasonable pharmaceutical executive considers those factors in particular, and (iii) how applying those factors to the objective facts here would have made a reasonable pharmaceutical executive less likely to launch generic Lidoderm at-risk as of the time defendants settled their Lidoderm-related patent litigation. Murthy Oppo. [Dkt. No. 809] at 1. Defendants also point out that, contrary to plaintiffs' assertion, Murthy reviewed and relied on documents produced in this case, depositions taken in this case, as well as publicly available documents. Ex. 2 to Murthy Report.

The motion to exclude is DENIED. Murthy's opinions on what pharmaceutical executives consider with respect to at-risk launch fall reasonably within Murthy's experience in the industry, and his opinions about whether a reasonable company in Watson's position would have launched at-risk (based on his understanding of the disputed facts, in light of the record evidence he reviewed), are also permissible.[44]

6. EPPs' Motion to Exclude Navarro

The EPPs move to exclude the September 2, 2016 Report of Dr. Robert Navarro that

[43] Specifically, plaintiffs seek to exclude paragraphs 13(a), 23-28, 37-50 and 52-57 of the Murthy Report. In 13(a), as an example, Murthy opines, "A generic company will consider many factors when evaluating whether to launch a product 'at risk,' including without limitations:
(i) the likelihood and timing of obtaining all regulatory approvals;
(ii) the likelihood of an adverse litigation outcome (including potential damages based on the magnitude of sales of the branded product—which could be trebled—and how an adverse ruling could affect "first to file" opportunities);
(iii) the company's manufacturing capabilities and ability to meet demand; and
(iv) the likelihood and timing of entry of additional generic manufacturers.
When evaluating the record relating to these factors, it is my opinion that it is very unlikely that a company in Watson's position would have launched a generic version of Endo's Lidoderm patch 'at risk.'" Murthy Report [Dkt. No. 809-2].

[44] In accordance with my prior Orders, defense experts will only be able to testify as to what "a reasonable" company would have done when faced with the (disputed) facts in this case, and not what Watson actually knew or was motivated by. *See, e.g.*, June 6, 2016 Minute Order [Dkt. No. 746] at 1.

discusses how payments flow for prescription drugs in managed care systems and responds to the opinions of plaintiffs' expert W. Paul DeBree on the same. As explained in the briefing on the motions for class certification, Narvarro opined that: (1) "As a result of the individualized and complex nature" of contractual relationships in the "market for prescription drug benefits," individualized inquiry" is necessary to evaluate the "harm, if any" to class members from the conduct at issue and to "ascertain proposed class members"; (2) claims data, even if available, fails to properly reflect rebate data and thus the price paid by class members; and (3) Pharmacy Benefit Managers ("PBMs") may pay or reimburse for Lidoderm or generic lidocaine through "spread pricing" or guaranteed rebates. Navarro Report [Dkt. No. 550-35] ¶¶ 9-15. The EPPs argue, first, that Navarro's opinions were elicited to defeat class certification (on ascertainability) and, therefore, are irrelevant at this juncture. Second, they argue his opinions are unreliable and based on pure speculation that because PBM might bear theoretical risk from their spread pricing and rebate strategies, there is no evidence that any PBM in the class period actually suffered injury (as opposed to the EPPs) with respect to Lidoderm. Third, as a result, his testimony is unduly prejudicial and likely to confuse the jury.

Defendants respond that Navarro's opinions are based on his extensive experience in the industry and critical to injury and state law damages issues to show that some of the overcharges were either not passed onto the EPPs or absorbed in whole or in part by other parties. Defendants are correct that Navarro's testimony is not irrelevant. That said, plaintiffs are correct that the same defect in Narvarro's testimony that existed at class certification continues; while Narvarro identified a risk that PBMs could suffer all or some of the harm on a particular transaction for a particular drug because of their spread-pricing and rebate practices, he did not identify any instance of that happening with respect to Lidoderm (and plaintiffs' witnesses testified that there was no harm to PBMs in the relevant timeframe). Therefore, at trial, his testimony will be limited to the fact that PBMs could have borne the risk of injury, but he cannot opine that PBMs suffered harm on their Lidoderm transactions.

Defendants are also correct that in the class certification Order I recognized that Navarro's opinions could be relevant to apportionment of damages. February 21, 2017 Class Certification

Order [Dkt. No. 670] at 39 n.33. However, damages was not a focus of Navarro's expert report (as noted above, its primary if not sole purpose was to undermine ascertainability) and is mentioned only twice in passing. Narvarro also admitted at his deposition that he was not retained as a "damages expert." Navarro Depo. Tr. [Dkt. No. 834-2] at 131:10-14. That does not mean his testimony is wholly irrelevant to damages. As this juncture, I will not preclude limited testimony by Navarro – given his background and experience – into the relationships between PBMs and plan sponsors, as well as pharmacies and manufacturers, and how rebates play into the payment flows for prescription drugs.

7. Motion to Exclude Schaede

Plaintiffs seek to exclude the testimony proffered by the Teikoku entities of Professor Ulrike Schaede concerning Japanese business practices and how Teikoku's role and agreement with respect to the Settlement reflected typical Japanese business practices. Specifically, plaintiffs object to Schaede's opinions that: (i) Japanese business culture differs from Western business culture, in that Japanese business culture emphasizes long-term trade relationships built on trust and behavioral norms such as incremental commitment, obligation, loyalty, and intertemporal exchange of favors, and (ii) Teikoku's decisions—engaging Endo as a U.S. distributor, amending a supply agreement with Endo, giving Endo "substantial control" over patent infringement litigation, and entering the settlement agreement with Watson—are "entirely consistent with Japanese business practices, and understandable in light of what a typical Japanese company would perceive and do in this situation. Schaede Report [Dkt. No. 772-2].

Plaintiffs argue that these opinions have no relevance to the antitrust issues and that admission of the testimony would be unduly prejudicial and risk jury confusion under Rule 403. Plaintiffs surmise that Teikoku wants to introduce this testimony to show its "good motives" and reluctance to join the agreement but that it did so out of obligation. Plaintiffs contend that good motives are irrelevant, as is Teikoku's purported reluctance.

Teikoku responds that the purpose of Schaede's opinions is two-fold: to show that Teikoku did not have the "intent" to monopolize when it entered the agreement, relevant to the Section 2 Sherman Act claim; and to explain why Teikoku contributed to the Settlement (to preserve its

good relationship with Endo), which in its view is a traditional and legitimate settlement consideration under *Actavis* and a "justification" defense that cannot be precluded through a motion in limine. Teikoku Sur-Reply re Schaede [Dkt. No. 885].[45]

Both sides agree "intent" is an element of a Section 2 conspiracy to monopolize claim.[46] However, Schaede specifically admitted that her testimony was not relevant to Teikoku's *intent*:

> Q . . . Is the point of your testimony to infer Teikoku's intent in entering the settlement agreement?
> A No, it is not.
> Q What is the point of your testimony?
> A I am evaluating Teikoku's decision-making over time, in light of Japanese business practices, to assess whether those decisions can be explained by way of the norms and values of Japanese business practices.

Depo. Tr. of Ulrike Schaede [Dkt. No. 772-3] at 105:15-23. Therefore, Schaede's testimony is not admissible for that limited purpose.

As to justification, I disagree with Teikoku that plaintiffs should have moved for summary judgment to attempt to preclude Teikoku from putting on its "justification" defense and cannot do so by trying to exclude the Schaede opinion. Teikoku Sur-Reply re Schaede at 2-3. Plaintiffs, by moving to exclude Schaede's testimony as not relevant under the law, are not raising a "dispositive" issue that should have been raised in a summary judgment motion. Instead, exclusion of opinions that are irrelevant as a matter of law or contrary to the law is appropriate through the *Daubert* process. *See, e.g., Apple, Inc. v. Samsung Elecs. Co*., No. 11-CV-01846-LHK, 2012 WL 2571332, at *7 (N.D. Cal. June 30, 2012) (excluding expert opinions that are "contrary to the law" and therefore not helpful to the jury).[47]

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[45] Teikoku's motion for leave to file a sur-reply in opposition to plaintiffs' motion to exclude the Schaede testimony [Dkt. No. 885] is GRANTED. I have considered the arguments made by Teikoku in that Sur-Reply, as well as the responses made by plaintiffs' in their Opposition to the Motion for Leave. Dkt. No. 887.

[46] *See, e.g., Paladin Assocs., Inc. v. Montana Power Co*., 328 F.3d 1145, 1158 (9th Cir. 2003) (elements of a Section two claim are: "(1) the existence of a combination or conspiracy to monopolize; (2) an overt act in furtherance of the conspiracy; (3) the specific intent to monopolize; and (4) causal antitrust injury.").

[47] Plaintiffs are not, as in many of the cases cited by Teikoku, attempting a second "bite at the apple" after losing on an issue at summary judgment. *See, e.g., Venture Corp. v. Barrett*, No. 5:13-cv-03384-PSG, 2015 U.S. Dist. LEXIS 59477, at *11 (N.D. Cal. May 5, 2015); *cf. Guzik*

Finally, Teikoku's "maintain good relations with Endo" motivation for entering the Settlement Agreement is not a defense under *Actavis.* Teikoku points to no authority that recognizes anything other than pro-competitive justifications as defenses for otherwise anti-competitive agreements under *Actavis*. While the Supreme Court in *Actavis* expressly recognized at least two "traditional settlement considerations" that may account for a reverse payment – *e.g.*, "a rough approximation of the litigation expenses saved" or "compensation for other services that the generic has promised to perform" – and noted that "[t]here may be other justifications," those justification must be *relevant* to the "rule of reason" analysis. *F.T.C. v. Actavis, Inc*., 133 S. Ct. 2223, 2236 (2013); *see, e.g*., *Anderson v. Am. Auto. Ass'n*, 454 F.2d 1240, 1246 (9th Cir. 1972) ("The promotion of self-interest alone does not invoke the rule of reason to immunize otherwise illegal conduct. It is only if the conduct is not unlawful in its impact in the market place or if the self-interest coincides with the statutory concern with the preservation and promotion of competition that protection is achieved." (quoting *United States v. Arnold, Schwinn & Co*., 388 U.S. 365, 375 (1967) *overruled on other grounds by Cont'l T. V., Inc. v. GTE Sylvania Inc*., 433 U.S. 36 (1977)); *see also In re Lipitor Antitrust Litig*., 868 F.3d 231, 263 (3d Cir. 2017) ("intent is not an element of an antitrust claim, and benign intent does not shield anticompetitive conduct from liability."); *Levine v. Cent. Florida Med. Affiliates, Inc*., 72 F.3d 1538, 1552 (11th Cir. 1996) ("The rule of reason analysis is concerned with the actual or likely effects of defendants' behavior, not with the intent behind that behavior.").[48]

Tech. Enters. v. W. Digitial Corp., No. 5:11-cv-03786-PSG, 2013 U.S. Dist. LEXIS 171327, at *28 (N.D. Cal. Nov. 22, 2013). (denying motion in limine seeking to preclude claim of infringement by importation as "thinly-veiled" dispositive motion, but granting motion in limine to preclude evidence regarding willfulness, despite failure to seek summary judgment ton that issue, where willfulness was irrelevant as a matter of law). Nor are they seeking to exclude testimony on the ground that it was inadequately disclosed where there were other more appropriate remedies (*e.g*., motions to compel). *See, e.g., Nortek Air Sols., LLC v. Energy Lab Corp*., No. 14-cv-02919-BLF, 2016 U.S. Dist. LEXIS 92468, at *6 (N.D. Cal. July 15, 2016).

[48] Given the apparent lack of case law supporting Teikoku's position (that its benign intent is a defense under the rule of reason), Teikoku takes a different tack, arguing that *judicial estoppel* prevents plaintiffs from arguing intent is not relevant. Teikoku Opp. to Schaede at 7-9. However, that pro-competitive justifications are relevant (*e.g*., where a generic manufacturer provides distribution services) and anti-competitive justifications are relevant (*e.g.,* defendants were paying for delay of generic entry) does not mean that other justifications that have nothing to do with competition are relevant. Plaintiffs' repeated efforts to force Teikoku (or have me force Teikoku)

While maintaining good business relations with Endo might have been a key goal of Teikoku, Teikoku does not show how that goal has any pro-competitive impact on consumers or on the industry in general, or on any other consideration relevant to a rule of reason analysis. That justification, if true, does nothing to negate the inference (or according to plaintiffs, the actuality) that the payments agreed to by Endo and Teikoku were to delay competition.

Plaintiffs' motion to exclude the testimony of Ulrike Schaede is GRANTED, as that testimony is irrelevant and will not assist the trier of fact.[49]

C. Defendants' Motions

1. Motion to Exclude Adelman & Shah

Defendants move to exclude in part the opinions of plaintiffs' experts Professor Martin Adelman [Dkt. No. 819-13] and Dr. Kishore Shah [Dkt. No. 819-15], who offer expert testimony on what would have been the likely outcome of the '529 patent litigation, on the grounds that those experts' opinions are divorced from the record evidence in the '529 trial. Dkt. No. 780.

Adelman. Defendants move to exclude Adelman's opinions on validity and enforceability. Defendants argue that because he did not opine on how Judge Sleet or the Federal Circuit would have decided validity and enforceability, but instead analyzed validity and enforceability as a "reasonable factfinder," his opinions are based on the wrong legal standard. Defendants posit that Adelman used the "reasonable factfinder" construct to avoid statements made by Judge Sleet on the credibility of witnesses that would, if considered, undermine Adelman's opinions. Adelman & Shah Mot. at 4. Defendants also complain that Adelman makes an argument on enforceability (regarding misleading statements made by Teikoku in declarations and responses to the PTO) that was not made at trial.

In his deposition, Adelman explains that "reasonable factfinder" was short hand for how

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to produce attorney-client information in discovery to uncover Teikoku's true purposes for entering the Agreement does not estop plaintiffs from arguing that the Schaede testimony is irrelevant.

[49] For similar reasons, even though the plaintiffs did not move to exclude it, testimony from Moffitt about "maintaining a good business relationship" as a "traditional settlement consideration" will not be allowed. Moffitt Rep. ¶¶ 72-73.

the factfinder in the first instance (as anticipation is a question of fact) should have and then the Federal Circuit on appeal (under a clearly erroneous standard of review) would have decided the validity question. Adelman Depo. Tr. [Dkt. No. 817-2] at 70:12-16; 101:15-21. When discussing questions of law, like obviousness and inequitable conduct, Adelman referred to "the court" (including the Federal Circuit on review).[50] Adelman Report ¶ 39.

As to Judge Sleet's comments that Adelman supposedly ignored, I do not find them as certain or persuasive as defendants assert. While Judge Sleet asked a question about the significance and impact of a decision to credit Endo's witness (Lane) over Watson's (Walters) on some undisclosed bases and issues, it was phrased as a question and by no means indicates how Judge Sleet was going to credit the testimony, let alone how he would rule. As to the credibility that Judge Sleet found (much more affirmatively and specifically) concerning the '529 inventor (Ono), even though Judge Sleet found Ono credible, that does not answer the question of how he would have ruled on the intent to deceive issue with respect to Ono's representations made to the PTO. Indeed, as plaintiffs point out, Judge Sleet also expressly acknowledged that he could *infer* intent and recognized the important policy considerations at play that encourage full disclosure of prior art to the PTO. Closing Argument Tr. 105. While all experts agree that Judge Sleet was going to find infringement in light of his comments and claim construction order, defendants point to no testimony or other indication how he was going to decide validity or enforceability other

[50] Defendants are correct that Adelman was not emphatic about what a reasonable factfinder/Judge Sleet/the Federal Circuit would have done on anticipation, but he *was* clear about what "the courts" should have (in the case of Judge Sleet) or would have (in the case of the Federal Circuit) done with respect to obviousness *based on the record in the underlying case*. *See id*. at 155 (responding to the question of whether "court" included reasonable factfinder or Judge Sleet:

> A. I did not make that distinction. So I was talking about the -- really the courts, including the Federal Circuit. And in that, I'm assuming that the Federal Circuit would look at it as – the same as KSR. And I would have expected Judge Sleet to do the same. But that doesn't always happen.
>
> A. I'm offering the opinion that he should have, and the combination of Judge Sleet and the Federal Circuit would have, under these facts, these -- and every one of these cases is different -- that, as I said before, the evidence is overwhelming on obviousness, and I believe it is on inequitable conduct.

Adelman Depo. Tr. at 154-55.

than the two statements identified above, which do not bear the weight defendants put on them.[51]

Finally, as to the "new" argument Adelman makes that was, according to defendants, not argued by Watson – that Teikoku knowingly submitted materially misleading declarations to the PTO – plaintiffs point out that Watson argued in closing that the declarations submitted to the PTO focused on the "unique" nature of the patches claimed in the patent application and how that was indisputably not true in light of Ono's own prior art, even if Watson did not use the term "misleading." Closing Argument Tr. at 94-96; *see also* Adelman Depo. Tr. at 253:8 – 254:19. That is sufficient to support Adelman's testimony.

The motion regarding Adelman is DENIED.

Shah. Defendants argue that Shah reached outside the closed record of the '529 patent litigation to form his opinions on whether the '529 patent was valid and enforceable. Shah testified that his opinions were based on the trial court record as well as his own "technical assessment of the case." Shaw Depo. Tr. [Dkt. No. 817-7]. As Shah explained in his deposition, because he was applying his scientific background and knowledge to his review of the trial record, his opinions were informed by scientific literature. *Id*. at 21. Shah also explained that he relied on specific references (outside of the '529 record), but only to explain the "technology" background (and not as prior art references to the '529 patent) and those references did not impact his decision as to the '529 patent's validity or enforceability. *Id*. at 95-96 (as background); 103 (book cited in report for background but did not "impact my opinion about the validity or invalidity"). Shah's reliance on his general knowledge and on specific references outside of the '529 record to explain the context for the technology at issue was not impermissible, especially given his clear statement that these additional references did not impact his opinions as to the '529 patent's validity or enforceability.

Defendants also argue that Shah's refusal in his deposition to say whether his opinions would change if he were limited to the "trial testimony" was an admission that he relied on

[51] Even if Judge Sleet's credibility comments were as strong and set in stone as defendants contend, defendants do not explain how they would impact obviousness (which is determined as a matter of law).

materials outside the trial record for his opinions. Adelman & Shah Mot. at 7. But this "concession" is not as strong as defendants would hope. On its face, "trial testimony" doesn't necessarily include all of the *evidence* before the '529 trial court (and available for the Federal Circuit's review on appeal). Shah also repeatedly clarified that he was asked to look at "all the information" and "all of the references" to give his opinions. Shah Depo. Tr. at 129, 130. But nowhere in his deposition were defendants able to identify a particular reference or piece of information that was verifiably outside the scope of the '529 record that Shah *relied upon* to form his opinion on validity and enforceability as to the '529 patent.[52]

The motion to exclude is DENIED as to Shah.

2. Motion to Exclude Elhauge

Defendants move to exclude the opinions of Professor Einer Elhauge, a law professor who opines in support of plaintiffs' alternate causation theory that in the hypothetical but-for world, even without a reverse payment the defendants would have agreed to a settlement allowing Watson into the market nearly a year earlier than the date on which the parties agreed in the real world. Elhauge Mot. [Dkt. No. 783].

Elhauge first estimated the parties' bargaining strength using the actual Settlement. He then used that estimation of strength, and the companies' own profit projections, to opine that if Endo thought it had more than a 15.1% chance of winning, it would not have rationally agreed to the actual Settlement. Elhauge Report [Dkt. No. 819-2] ¶¶ 6, 147. Then he considered the various possible strengths each party could have rationally had with respect to the litigation to produce a range of feasible no-reverse-payment settlement early entry dates that still would have provided each party with a payoff exceeding its litigation payoff. *Id.* ¶¶ 8, 149-153.

Defendants argue that this "model" of Elhauge's own invention was described by the Retailer Plaintiffs' expert (Leffler) as "not transparent" and "difficult to understand." Because of its complexity and lack of transparency, defendants argue it should be excluded. *See Oracle Am.,*

[52] Plaintiffs also argue that the "background" references included in Shah's Report were not limited to the '529 technology but were also relevant to Shah's opinions on the Rolf patents. Adelman & Shah Oppo. at 9. Defendants do not address or contest this position in their Reply.

Inc. v. Google Inc., 798 F. Supp. 2d 1111, 1119–20 (N.D. Cal. 2011) (adopting "the normal *Georgia–Pacific* factors" and rejecting adoption of a mathematical model for juror use to determine reasonably royalties where the model "has never been approved by a judge to calculate reasonable royalties in litigation, at least in the face of objection. This is despite the fact that for decades it has been lurking in the field of economics. The [] solution involves complex mathematical formulas and equations that would surely be incomprehensible to the average juror.").

Defendants also argue that the model should be excluded because it has not been tested or peer reviewed. Elhauge admitted that the model he used in this case was a combination of principles published in at least three different articles (according to defendants, two of which were student-run, not peer reviewed, and did not address bargaining strength, and the third addressed "patent holdup" and "royalty stacking," not bargaining strength). Elhauge also conceded that he was unaware of any study that "validated" the idea that bargaining strength derived from one settlement can be used to predict the outcome of an alternative negotiation. Elhauge Depo. Tr. 114:23-115:23. Defendants rely on *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 52 (1st Cir. 2016), where the court concluded it was not an abuse of discretion to exclude a methodology, purporting to use stock market date to estimate a but-for entry date, where the data and model "did not fit the conclusions for which it was offered" and where no one else had ever used the method to predict settlement terms, except in "an unpublished, non-peer-reviewed working paper" that the expert had co-authored during the course of the litigation." *Id.* at 52.

In general, I note that numerous courts have admitted testimony from Elhauge as an expert in antitrust economics generally, although some have excluded his testimony where it was based on unreliable assumptions as to market definitions or because of problems in his regression analysis. *See, e.g.*, *In re Mushroom Direct Purchaser Antitrust Litig.*, No. 06-0620, 2015 WL 5767415, at *4 (E.D. Pa. July 29, 2015) (admitting Elhauge's testimony and noting, "[t]here is no dispute that setting aside the issue of regression analysis in particular, courts have admitted Prof. Elhauge as an expert in antitrust economics generally."); *It's My Party, Inc. v. Live Nat., Inc.*, 88 F. Supp. 3d 475, 488 (D. Md. 2015), *aff'd sub nom. It's My Party, Inc. v. Live Nation, Inc.*, 811 F.3d

676 (4th Cir. 2016) (excluding Elhauge's definition of market power because "the methods utilized by Elhauge to create a category of artists who 'prefer amphitheaters' is unreliable").

While defendants are correct that Elhauge could point to no other case where an expert has employed the exact model he employs here, both the components of his model (estimating parties' bargaining strengths and expectations of patent strength) and the assumptions that go with it (the parties' own pre-settlement forecasts) are consistent with accepted economic theory and well-established principles. As to Elhauge's use of the "event study" based on an analysis of stock market gains, while a similar study was excluded in *In re Nexium*, 842 F.3d at 52, Elhauge uses the study here as only a "back stop" to corroborate his bargaining strength conclusions. Elhauge Report ¶¶ 89, 141. Standing alone, it is not the basis for his model and opinions.

Defendants do not point to any irrational outcomes (or outcomes that are contrary to profit maximizing assumptions in a but-for world) that flow from Elhauge's analysis. Defendants will be free to mount attacks on Elhauge's approach – deriving the bargaining strengths in his suggested but-for early entry settlement based on his analysis of the parties' actual bargaining strengths as represented by the Settlement they actually reached – in their cross-examination.

Elhauge may opine that in his view the parties would have been rationally motivated to agree to settlement allowing Watson early entry by specific dates. However, Elhauge cannot testify that the parties *would have* agreed to entry on a date certain, as that impinges on a determination left up to the jury. Defendants' motion is otherwise DENIED.

3. Motion to Exclude Hardigan

Defendants move to exclude the opinions of Peter J. Hardigan, plaintiffs' designated expert to opine on the amount of litigation expenses (including trial and appellate expenses) that defendants saved by settling the two pending patent infringement cases relating to Lidoderm, the '529 litigation and the "Rolf litigation" *Endo Pharmaceuticals Inc. v. Watson Laboratories, Inc*., No. 1:11-cv-00575 (D. Del.). Hardigan Mot. [Dkt. No. 785] at 1.

Defendants attack the qualifications of Hardigan, as he is neither a lawyer nor an expert in

patent law but instead works in patent and patent litigation investing.[53] Defendants complain that Hardigan did not examine the patents or the record involved in either the '529 or the Rolf patent litigations. Accordingly, they argue that his opinions – about projected appellate costs based on a belief that Endo/Teikoku would have lost at the trial court in the '529 case and that the Rolf case would have been less expensive to litigate given that it was related to the '529 litigation (which defendants contest) – are examples of why his analysis is unreliable and excludable.

As an initial matter, plaintiffs confirm that Hardigan will not be opining on whether Watson *would* have won at the trial court; his analyses are based on that assumption. With respect to the Rolf litigation, Hardigan did not simply rest on his understanding that the two lawsuits were closely related and could generate cost efficiencies. He started with the '529 litigation costs as a "significant input" for his analysis of the Rolf costs, but also looked to defendants' documents and deposition testimony regarding costs budgeted and (where data was provided) actually incurred at specific rates and stages of the two cases in order to help him reach his ultimate conclusions. For example, he noted that Watson budgeted (and at various stages incurred) less costs for the Rolf case than the '529 case. Hardigan Report ¶¶ 3.1, 5.1 – 5.4. He also "back stopped" his analyses by comparing them to the American Intellectual Property Associations publication on median ANDA litigations costs. Hardigan Report ¶ 6.1. Defendants do not point to any of Hardigan's calculations as misstating the evidence or argue that he came up with unreasonable estimates (*e.g.*, Hardigan's estimate that the Rolf litigation would have cost Endo $7.9 million, less that the estimated costs for the '529 patent but still more than the median costs to try an ANDA case). *Id.* ¶ 6.1. Hardigan did use the expenses occurred through trial in the '529 patent as a benchmark for his Rolf patent estimates, but did not rely exclusively on the "relatedness" between the two. Defendants may use that issue – and their belief that Hardigan relied too heavily on it – as a basis

[53] Hardigan describes himself as "an independent consultant" who is an executive and advisor to companies that engage in IP litigation with over 15 years of experience. He has been personally responsible for investment in and management of over 50 U.S. patent cases and has provide a range of IP advisory services to attorneys, Fortune 500 companies, and institutional investors engaged in patent licensing, patent transactions, and patent litigation. Hardigan Report [Dkt. No. 785-2] ¶ 1.1.

for cross-examination. [54]

As to his ability to predict and experience in predicting costs made on those types of assumptions, defendants complain that Hardigan's only prior experience on cases that went to trial were two cases that did not involve pharmaceuticals. Plaintiffs counter that Hardigan has estimated litigation costs for hundreds of projects. More specifically, for the (at least) 50 patent litigation cases he managed, even where a contingency or flat fee arrangement was adopted, Hardigan estimated what the legal fees would be by each stage of the case on a "full fee" basis. Hardigan Depo. Tr. [801-2] at 156-57. Defendants do not explain why his limited direct experience with pharmaceutical patent litigations undermines his ability to estimate costs here. Given the record evidence he considered as well as relevant publications, he has sufficient expertise and knowledge to estimate legal fees for this type of litigation.

The motion to exclude is DENIED, except (as noted above and agreed-to by plaintiffs) Hardigan will not be allowed to testify on the likely outcome of the '529 litigation.

4. Motion to Exclude Leffler

Defendants move to exclude the opinions of Dr. Keith B. Leffler in support of plaintiffs' alternate causation theory that in the hypothetical but-for world, but-for the reverse payment, the defendants nonetheless would have agreed to a settlement allowing Watson into the market on a date before its actual September 15, 2013 entry. Dkt. No. 782; Dkt. No. 782-2 (Leffler Report).

Leffler started his analysis by evaluating the expected profits from litigation as opposed to an alternative settlement, an analysis approved by a large amount of economic literature. He calculated Endo's profits from winning or losing the patent litigation and "weighted" the alternatives by the objective expectations (from Adelman's opinion) that Endo would win or lose. Leffler Report ¶ 80. He initially concluded that Watson would have accepted a no-payment settlement allowing it early entry in October 2012. *Id.* ¶ 82. When considering the testimony of plaintiffs' manufacturing witness (Miller) that Watson would not have had sufficient launch

[54] Defendants do not argue that *no* efficiencies would flow from the '529 litigation to the Rolf litigation, but because that the same product (5% lidocaine patches) was involved, the same counsel were involved, and the same court was involved certainly there would be some. How many and how significant those efficiencies may have been can be tested at trial.

quantities by that date, Leffler revised his estimate to a later date. *Id*. ¶ 83.

Defendants argue that Leffler's analyses must be excluded because there is no peer-review published article that teaches taking standard and accepted economic analyses of settlements and applying them in a way to predict early entry in this sort of case. Leffler Mot. at 5-6. However, as with the challenge to Elhauge, that prior experts or academics have not combined different but *accepted* economic theories and modes of analysis for patent settlements and then applied them to this specific set of facts – which are unique in the relatedness between the actual Settlement and consideration that the identical parties are essentially identically situated – is not surprising and does not require exclusion. *See* Leffler Depo. Tr. [Dkt. No. 782-4] at 184 (the "details" of this model are specific to the facts of this case, although the conceptual underpinnings are from economic literature).[55]

Defendants also argue that Leffler's opinions are somehow based on an impermissible inference that an anticompetitive effect can be inferred from simply the large reverse payment, which in defendants' view is impermissible under *Wellbutrin*. Leffler Mot. at 6. As noted earlier, I have concluded that the large and unexplained nature of the reverse-settlement payment (if established) is particularly relevant evidence even if not sufficient on its own. Moreover, Leffler explained that he did not rest solely on the inference, but also considered the terms of the actual settlement and the parties' expectations of the outcome of the litigation. Leffler Depo. Tr. 128-29.

Defendants criticize Leffler's reliance on Adelman's estimate of the low likelihood that Endo would win the patent litigation because he did not test that figure/assumption himself and only received that figure the day before his report was due. As explained above, Adelman's opinions have not been excluded and are subject to testing at trial. As to the timing, Leffler

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[55] The full exchange at issue reads:

> Q. From any of this literature, did you, for lack of a better term, "pluck off" the shelf a model and implement it here in this report?
>
> . . .
>
> THE WITNESS: No. The details of these would be very, very specific to the situation so the answer is no in the sense I think you're asking the question. If you mean just in a more conceptual sense of considering the gains from litigation and then considering the gains from settlement, then the answer is yes, but not specifically grabbing an existing set of analyses and changing a number here or there.

Leffler Depo. Tr. at 184:3-18.

explained in his deposition that he created his model and used a placeholder for the Adelman figure and was able to test different inputs in his model, but inserted the final figure when he received it shortly before his report was due. Leffler Depo. Tr. 211 – 213. There is nothing improper about this approach.

Finally, defendants argue Leffler's opinions must be excluded because they are not based on sufficient facts in the record. This is the same argument made above. Because this case is set in a but-for world, it is not surprising that no evidence shows that defendants were contemplating anything other than the actual Settlement. Leffler's failure to address (or adequately address) various factors that defendants believed would impact Watson's actual ability to launch (status of Endo's Citizen Petition, Watson's manufacturing capacity, Teikoku's willingness to enter into a settlement) can be addressed on cross-examination.

Leffler may opine that the parties would have been economically motivated to enter into a no-payment settlement as of a particular date or within a range of dates. He cannot testify that the parties would have entered on a date certain, as that impinges on a determination left up to the jury. Defendants' motion is otherwise DENIED.

5. Motion to Exclude Miller

Defendants move to exclude the opinions of Dr. Kenneth Miller, who opines that in the but-for world, Watson would have manufactured the 23 million patches earlier than it actually did. Dkt. No. 793; Miller Report [Dkt. No. 793-2]. Miller's opinions rest on two assumptions: (i) Watson could and would have manufactured sufficient launch quantities by December 17, 2012 had it continued production and not stopped in June 2012; and (ii) even if Watson stopped in June 2012 and restarted in November 2012 after correcting manufacturing issues (what actually happened), Watson would have had sufficient launch quantities by January 2013, as long as it employed profit-maximizing strategies, including delaying a plant closure and working through the holidays.

Defendants first argue that Miller's failure to fully explain his experience in patch manufacturing in his deposition prevented defendants from fully testing the reliability of his opinions. Defendants point out that Miller testified that he was involved with the development of

a hydrogel patch, but he would not provide specifics because of confidentiality concerns and only responded that "he had never been involved in the development of a hydrogel that has become a commercial product." Miller Depo. Tr. [Dkt. No. 793-4] at 62. The exchange continued:

> Q. So in providing your testimony on behalf of plaintiffs in this case, should we assume that you are not drawing upon your experience with respect to this hydrogel patch product?
> A. I am drawing upon my experience. My experience of understanding the chemistry that is at play here. My understanding of the mixing processes, and the coating processes, and the packaging processes. Because those unit operations are all the same. They operate on the same principles, using the same types of equipment for a matrix patch or for the case at hand, this Lidocaine patch.
> Q. Okay. So I'm going to ask again. In what prospect have you been involved in the development of a hydrogel patch product?
> []
> THE WITNESS: I am uncomfortable answering a question about products that I may or may not have worked on in the past because that is all confidential information.

Miller Depo. Tr. at 63. Defendants also complain that Miller failed to answer specific questions as to the exact mix, mix process, and application to a patch for a patch he worked on at Mylan, although Miller did respond with general answers about those processes. *Id*. at 36-37. Miller also refused to identify the date that Mylan started working on a lidocaine patch. *Id*. at 45-46. Finally, defendants complain that while Miller opined based on his experience that pharmaceutical companies would cancel vacations, holidays, and plant shut downs, he refused to disclose with which companies he had experiences with on those topics. *Id*. at 184-85.

Plaintiffs respond that Miller testified extensively about his experiences with matrix patches, including the Mylan patches that Miller initially expressed confidentiality concerns about before going on to testify fully about the general process of manufacturing them. Miller Depo. Tr. at 36:6 – 37:13. According to plaintiffs, Miller's experience with matrix patches is transferrable to hydrogel patches, so that his few limited confidentiality assertions on his experience with hydrogel patches is not a problem. Miller Oppo. at 2. As to his experience with plant operations (in order to rush product production), plaintiffs argue that because Miller identified the two companies he had worked at full-time (Mylan and Noven), and also went onto disclose that Mylan had one plantwide shutdown during his time and that he knew of instances where Mylan cancelled

vacations due to production demands, the bases for his opinions have been disclosed. 184-86, 188-89, 192-93.

Generally, reviewing his testimony as a whole, I find that Miller disclosed enough about his experience with matrix and hydrogel patches to allow defendants to test his level of experience.[56]

Defendants also move to exclude Miller's opinions on what Watson "would have done" because Miller has no relevant expertise on those subjects, including his purported profit-maximizing strategies. While Miller admitted that he had not been responsive for "pulling the switch and manufacturing a first commercial batch that I signed off on, I will grant you that. No, I haven't done that[]", Miller Depo. Tr. at 60, he went onto explain, that "there are a lot of processes that occurred before that that are at that level of responsibility." Miller Depo. Tr. at 60; *see also* at 61 (testifying to his "extensive involvement in" pre-commercial production and that he "had many responsibilities throughout the organization and they did involve whether or not products were commercially manufactured and how that was done."). As to employee schedules, he testified that he did not set company calendars, but he did have employees work through holidays "for him" and had knowledge of companies' practice in the area. *Id*. at 62.[57] Again, read in full, Miller's experiences are sufficient to allow him to opine on these subjects, but defendants will be free to challenge Miller's lack of experience on particular decision-making points during cross-examination.

On the related point of Miller's interpretation of Watson's documents and his reliance on those documents in support of his but-for theories, I conclude that Miller's testimony synthesizing the various technical and non-technical documents is appropriate.

[56] This ruling does not preclude defendants from objecting to and moving to strike particular testimony if Miller asserts confidentiality concerns as a basis to refuse to answer questions at trial or if Miller testifies on matters at trial that he refused to testify on during his deposition.

[57] Miller testified that he had never been involved in setting the amount of product required for product launch. Miller Depo. Tr. at 59. But in this case, Miller's opinion is based on Watson's own documents indicating various launch date quantity scenarios. His lack of direct experience in this area is not problematic.

With respect to Miller's alternate January 28, 2013 launch scenario, defendants argue that Miller admitted in his deposition (contrary to his Report) that his maximizing-theory (*e.g.*, working through holidays and cancelling plant shutdowns) would not have allowed Watson to manufacture enough quantity by January 28, 2013, so his opinion is without basis. But as Miller explained, his theory is based on Watson's own projections of two batches a week and having staff "work every day" (not just over the holidays) to meet those projections. Miller Depo. Tr. 197-98. The justification in his deposition is consistent with his theory of maximizing strategies from his Report.[58]

Finally, defendants move to exclude Miller's opinions about claim construction and infringement, as he is a chemical engineer with no relevant experience. They contend that testimony by Miller as to claim construction and literal or doctrine of equivalents (DOE) infringement would be outside of the record of the actual '529 litigation because: (1) Watson did not present a technical expert on claim construction; (2) Miller's opinion on literal infringement is based on an undisputed fact; and (3) Miller cannot make doctrine of equivalents arguments that were not made by Watson. Plaintiffs initially note Miller's qualifications and argue that his testimony is admissible (and appropriate) because he is simply responding to the arguments presented by defendants *in this case* by their expert (Majella Lane, who was Endo/Teikoku's expert in the '529 litigation). In doing so, Miller relies on evidence and arguments (as to claim construction) actually made by Watson in the '529 litigation (even if not presented through a "technical expert") and disputed in that case between Miller and Lane (as to literal infringement). *See, e.g.*, Miller Reply Report [Dkt. No. 816-8] ¶¶ 15-20. This testimony is admissible.

Miller's testimony regarding the doctrine of equivalents purports to answer questions of law (no infringement under the DOE due to vitiation, disclosure-dedication, or prosecution history estoppel). It falls outside of his area of expertise and he cannot opine on the ultimate legal conclusions that may have been reached in the '529 litigation. He can, however, dispute the

[58] In his Report, Miller gives examples of how Watson could have "squeezed" extra "man-hours" out of its manufacturing process. Miller Report ¶¶ 41, 300-301. As to the two-batches-a-week projection, defendants can attack Miller's basis for believing that projection was realistic or actually viable.

factual issues (for example, he can contest Lane's analysis based on "principles of pharmaceutical formulation") and opine on what a person of ordinary skill in the art would have known or how she would have viewed the Teikoku file history (as relevant to legal questions arising under the DOE).

Other than the objection to Miller's testimony on questions of law under the doctrine of equivalents, defendants' motion is DENIED.

6. Motion to Exclude Molina

Defendants move to exclude the opinions of Luis Molina that in absence of the Settlement, Watson would have launched at-risk and Endo would have launched its Authorized Generic (AG) immediately after Watson's launch. Defendants argue that Molina lacks the background and experience to opine on these subjects because while he provided input on these sorts of decisions, he was not the final decision-maker or included in the senior management's decision-making. Defendants also object to Molina's testimony about the "intent" of Watson and Endo regarding their launch plans, arguing that intent and state of mind are not appropriate areas for expert testimony. Finally, defendants object to Molina's "interpretation" of disputed facts, contending Molina is attempting to usurp the factfinder's role at trial.

On experience, defendants make much of the fact that Molina was never involved in deciding whether to launch a generic at-risk, was never the ultimate decision-maker on whether to launch an AG, never had specific responsibility concerning patent litigation, and had never presented his financial information directly to a Board or investors. Molina Mot. at 3-6. However, Molina bases his opinion on Watson's likelihood of launching at-risk on statements made by Watson employees and executives and also on evidence regarding the steps Watson took towards manufacturing their generic patch before and after the Settlement, evidence that in his view was consistent with the actions of a company preparing to launch at-risk. Molina Report [Dkt. No. 777-5] ¶ 17.[59] While Molina admitted that he had no first-hand experience with at-risk

[59] Defendants also complain about Molina's testimony regarding defense-expert Murthy's treatment of the patent-litigation risk in Murthy's Report. *See* Molina Reply Rep. ¶¶ 96-102. It is unclear whether Molina or Murthy have experience sufficient to testify as to how reasonable companies would weigh patent-risk in deciding to launch, but those objections can be made at trial

launch and while defendants contend that Molina ignores the possibility Watson's public statements were "posturing," his background in analyzing the likelihood of potential generic competition and his own efforts in launching authorized generics gives him the experience to opine on the indicators that show a company was preparing to launch a product and whether they existed here. *See, e.g.*, Molina Rep. ¶ 54. Defendants agree that Molina has direct experience with AG launches, but note that Molina never operated at the "senior executive" level and never made high-level presentations (to the Board or to investors) regarding AG launch, although information prepared by Molina was presented at these levels. Molina Mot. at 5-7. But given Molina's experience in the industry, he is qualified to opine on this subject based on his review of the evidence.

Molina's testimony concerning Watson and Endo's "intent" is about what he believed Watson and Endo were prepared to do prior to the Settlement based on his review of the record evidence. It is not the type of "motivation" or "state of mind" testimony that courts have excluded.[60] As made clear in his reply, Molina relied on his industry experience and the evidence he reviewed that Watson was preparing for an expeditious launch, but did not opine on what Watson executives subjectively decided, thought, believed, or intended. Molina Reply Rep. ¶ 69. If Molina veers into purely speculative opinions on the subjective motivations or beliefs of employees or executives at Watson or Endo at trial, objections may be made and sustained. In light of his experience in the industry, Molina is allowed to opine that Watson and Endo had decided to launch generics, given the steps those companies had taken and the public and non-

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if that sort of testimony is elicited and an appropriate foundation is not laid.

[60] *See, e.g., Stanley v. Novartis Pharmaceuticals Corp.*, 2014 WL 12573393, at *6 (C.D.Cal., 2014), quoting *In re Rezulin Products Liability Litigation*, 309 F.Supp.2d 531, 547 (S.D.N.Y. 2004) (excluding "speculative inferences" about defendants' motivations); *In re Flonase Antitrust Litigation*, 884 F.Supp.2d 184, 193 (E.D.P.A. 2012 (experts not permitted to testify as to "state of mind" as to why a company filed its citizen petition); *In re Fosamax Products Liability Litigation*, 645 F.Supp.2d 164, 192 (S.D.N.Y. 2009) ("To the extent Merck's motion seeks to preclude Dr. Parisian from testifying as to the knowledge, motivations, intent, state of mind, or purposes of Merck, its employees, the FDA, or FDA officials, it is GRANTED. Dr. Parisian conceded at the hearing that her regulatory expertise does not give her the ability to read minds. Nevertheless, her report is replete with such conjecture."); *see also Siring v. Oregon State Bd. of Higher Educ. ex rel. Eastern Oregon University*, 927 F.Supp.2d 1069, 1077 (D. Or. 2013) (collecting cases).

public comments that were made.

Finally, plaintiffs will not be allowed to elicit testimony from Molina for the sole purpose of entering a factual narrative in the record. He will, of course, be allowed to identify the facts (documents, testimony) that support his otherwise permissible opinions. Defendants are free to challenge Molina on the stand regarding his interpretations of those documents and testimony.

Defendants' motion to exclude Molina is DENIED.

7. Motion to Exclude Read

Defendants move to exclude the opinions of David T. Read, a lawyer at the U.S. Food and Drug Administration (FDA) until 2015. Dkt. No. 779. Defendants argue that because Read participated in FDA ANDA discussions, including discussion about Watson's ANDA and because Read signed off on the FDA's eventual approval of Watson's ANDA, Read's personal knowledge and participation blurs the line between expert and lay testimony and risks misleading the jury or elevating him in their estimations. Defendants also complain that Read refused to disclose in his deposition specifics of certain internal FDA discussions (at counsel's advice, based on concerns that to do so would violate confidentiality obligations) and, therefore, defendants were unable to adequately test Read's experiential qualifications and fully test his opinions.

Plaintiffs respond that Read is testifying only as to one, limited issue: whether the non-interference provision in the Settlement (where Endo agreed to not further amend or otherwise pursue its Citizen Petition with the FDA) sped up the denial of the Citizen Petition, and relatedly that the Citizen Petition was not acting as a barrier to Watson's ANDA.[61] Plaintiffs argue that in order to manufacture a conflict (and this motion), defense counsel attempted to ask Read questions about his work on ANDAs generally and Watson's ANDA specifically. Read objected to some questions on the basis of the deliberate process privilege but provided limited testimony about his

[61] Read Report [Dkt. No. 779-2] ¶ 15 ("I have been asked by counsel to review the facts and circumstances concerning the disposition of Endo's citizen petition and related amendments, and to render an opinion on whether the purported notification to FDA by Watson of the existence of the so-called non-interference provision in the settlement agreement between Endo and Watson accelerated FDA's denial of Endo's citizen petition."). Plaintiffs argue this testimony may not be necessary because defendants have no admissible evidence that the FDA knew about the non-interference provision.

ministerial role in signing off on the Watson ANDA approval letter.[62] Those few instances of assertions of privilege, according to plaintiffs, were to information that was irrelevant to Read's opinion on the non-interference provision.

Read asserted in his deposition that he had no involvement in the resolution of the Endo Citizen Petition. Depo Tr. [Dkt. No. 818-21] at 104. His involvement with Watson's ANDA was limited to reviewing and signing off on the approval letter, with his focus directed to the language regarding the patent and regulatory exclusivity language. *Id*. at 50-55. He agreed generally that the FDA's treatment of and timing of work on Citizen Petitions and ANDA were interrelated. *Id*. at 125 ("Q These two issues, the Lidoderm ANDA that Watson filed and the Lidoderm citizen petition, those two issues in that sense are interrelated, correct? That's why they get decided "simultaneously," in your words, correct? A That's correct. Q They're interrelated, correct? A Yes.").

Read declined to answer questions about how competing ANDAs were handled with respect to Lovenox (while asserting that his testimony and knowledge were not relevant to how the Lovenox Citizen Petition was determined), *id*. at 92-98, as well as questions concerning whether the FDA had discussed or made a decision on whether and how exceptions to *forfeiture of exclusivity* might apply to the Watson ANDA. *Id*. at 225-226. He also indicated that he would not disclose the "conversations" he had with colleagues at the FDA about Citizen Petitions." *Id*. at 98-99; *see also id*. at 94 (expressing reticence to disclose nonpublic information). That said, defendants point to no questions relevant to the subjects Read is opining on – the impact of the non-inference Settlement provision on the FDA's determination of Endo's Citizen Petition and (according to his Report) more generally whether the Endo Citizen Petition acted as a barrier to Watson's ANDA – that he refused to answer based on his concern over the confidentiality or privilege covering internal FDA deliberations.

[62] As part of the background, Read does explain the FDA's internal review process for Citizen Petitions. *See generally* Read Report. Read's discussions about the timing of ANDA approvals is largely contextual and confined to his testimony that Citizen Petitions will usually be given a low priority unless there is a pending ANDA and if so, then the resolution of the Citizen Petition will typically be hinged to timing for the resolution of the ANDA. Read Report ¶¶ 38, 50.

While defendants are correct that plaintiffs' counsel repeatedly "cautioned" and reminded Read about confidentiality, in all but the two instances identified above, Read actually answered the questions asked. Defendants have not shown that Read refused to explain the bases for his opinions in this case based on confidentiality concerns. *See Sanchez v. Boston Scientific Corp*., 2014 WL 4851989 *12 (S.D.W.Va. 2014) (excluding expert testimony because expert's confidentiality obligations prevented him from explaining the bases for his opinions and, therefore, precluded testing the reliability of those opinions); *Gray v. Cottrell, Inc*., 2007 WL 4864393 *2 (E.D. Mo. 2007) (same). If at trial it becomes clear that Read's opinions *in this case* are based in part on his substantive review of the Watson's ANDA (which does not appear to be the case based on the current record) or are otherwise informed by *relevant* information over which Read asserts confidentiality, I will revisit the motion to exclude and or address specific objections and motions to strike. *See, e.g., In re Mirena IUD Products Liability Litigation*, 169 F.Supp.3d 396, 472 (S.D.N.Y. 2016) (excluding testimony of former agency employee who "personally participated" in agency actions at issue in the subsequent litigation, but only testimony concerning the time period where expert worked at agency).[63]

Defendants' motion is DENIED. However, defendants may re-raise this motion at the pretrial conference in light of the recently produced FOIA responses.[64]

V. PENDING ADMINISTRATIVE MOTIONS TO SEAL

There are numerous pending administrative motions to file under seal, filed in connection with Teikoku's Proffer [Dkt. Nos. 562]; plaintiffs' Motion to Strike [Dkt. Nos. 680, 681, 690,

[63] Read's position in a publicly run agency and the limited nature of his testimony distinguishes him from the expert excluded *in Gill v. Arab Bank, PLC*, 893 F.Supp.2d 523, 541-42 (E.D.C.A. 2012) (excluding testimony from employee of Israeli Security Agency as "[m]uch, if not all, of Mr. Shmilovitch's testimony is based on facts developed through confidential ISA investigations and investigatory methods. Any weight to Mr. Shmilovitch's testimony would be excessive in light of plaintiff's inability to adequately cross-examine Mr. Shmilovitch as to the basis of his conclusions.").

[64] In their Reply, defendants cite to FDA documents that were produced pursuant to a FOIA request but only received by defendants after they filed their initial motion. Defendants argue those documents show that Read was involved in the Endo Citizen Petition and had a more active role in shaping the Watson ANDA responses than he recalled in deposition. Read Reply [Dkt. No. 840] at 2-5. Plaintiffs have not had an opportunity to respond to the significance (if any) of those documents and arguments made by defendants.

692]; and the parties' motions for summary judgment and to exclude. [Dkt. Nos. 769-780, 782-783, 785-786, 793-794, 801-802, 804-807, 809-819, 833-835, 837-838, 840, 843-844, 846-854].

The parties are directed to meet and confer to prepare a joint chart showing what specific information – by ECF Dkt. No. (*e.g.*, 837, 837-1, 837-4) and page/line number therein for each docket entry – a party or third-party believes should continue to remain under seal. The chart shall cite, for each piece of information to remain sealed, to the docket number, paragraphs and/or line numbers from the declaration where a party, third-party, or other person with personal knowledge provides the justification for sealing.

The joint chart shall also identify – again by ECF Dkt. No. and sub-number (*e.g.*, 837-1, 837-4) – docket numbers that can be wholly unsealed because no party currently believes the information should remain under seal.

The joint chart shall be filed within 20 days of the date of this Order.

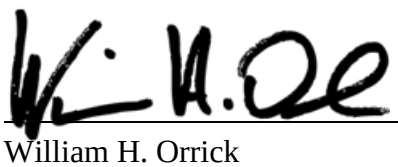
In reviewing the chart and declarations in support of continued sealing, I will apply the "compelling justification" standard, because the motions themselves (and the information discussed therein and sought to be sealed) have a significant connection to the merits of this litigation. Only specifically identified compelling justifications based on narrowly-tailored sealing requests will meet that high standard.

CONCLUSION

Defendants' motion for summary judgment as to all the claims is DENIED. Defendants' motion for partial summary judgment for findings of fact under Rule 56(g) as to causation is GRANTED. Plaintiffs' motion for partial summary judgment is GRANTED. The motions to exclude are resolved as indicated above.

IT IS SO ORDERED.

Dated: November 3, 2017



William H. Orrick
United States District Judge